Teklab, Inc.
Quality Assurance Manual

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See Table of Contents for major organizational units covered by this quality manual.

Table of Contents

SECTION 1 - INTRODUCTION AND SCOPE 6

1.1 TEKLAB INC 7
1.2 SCOPE OF TESTING 7
1.3 TABLE OF CONTENTS, REFERENCES AND APPENDICES 7
1.4 ACRONYMS 8
1.4.1 Acronyms 8
1.5 Management of the Quality Manual 9

SECTION 2 - ORGANIZATION 9

2.1 ORGANIZATION 10
2.2 CONFLICT OF INTEREST AND UNDUE PRESSURE 11

SECTION 3 - MANAGEMENT 11

3.1 MANAGEMENT REQUIREMENTS 11
3.2 MANAGEMENT ROLES AND RESPONSIBILITIES 12
3.2.1 Corporate: Chief Executive Officer / Chief Marketing Officer 12
3.2.2 Corporate: Laboratory Director 13
3.2.3 Corporate: President/Chief Financial Officer 14
3.2.4 Corporate: Technical Manager 14
3.2.5 Corporate: Quality Officer 15
3.2.6 Corporate: Director of Customer Service 16
3.2.7 Collinsville Air laboratory: Director of Operations/Analyst 16
3.3 QUALITY POLICY 17
3.4 ETHICS AND DATA INTEGRITY SYSTEM 18
3.5 DOCUMENTATION OF MANAGEMENT/QUALITY SYSTEM 18
3.5.1 Quality Manual (TNI 2009 V1M2 4.2.8.3) 18
3.5.2 Standard Operating Procedures (SOPs) 19
3.5.3 Order of Precedence 20

SECTION 4 - DOCUMENT CONTROL 20

4.1 CONTROLLED DOCUMENTS 20
4.1.1 Changes to Controlled Documents 21
4.1.1.2 Electronic Document Changes 22
4.2 OBSOLETE DOCUMENTS 22

SECTION 5 - CONTROL OF RECORDS 23

5.1 RECORDS MAINTAINED 23
5.2 RECORDS MANAGEMENT AND STORAGE 25
5.3 LEGAL CHAIN OF CUSTODY RECORDS 26

SECTION 6 – REVIEW OF REQUESTS, TENDERS AND CONTRACTS 27

SECTION 7 - PURCHASING SERVICES AND SUPPLIES 28

7.1 PROCEDURE FOR PURCHASING 28
7.2 APPROVAL OF SUPPLIERS 29

SECTION 8 - SUBCONTRACTING OF ENVIRONMENTAL TESTS 29

8.1 PROCEDURE 29

SECTION 9 - SERVICE TO THE CLIENT 30

9.1 CLIENT CONFIDENTIALITY 30
9.2 CLIENT SUPPORT 30
9.3 CLIENT FEEDBACK 31

SECTION 10 - COMPLAINTS 31

SECTION 11 - CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK 32

11.1 EXCEPTIONALLY PERMITTING DEPARTURES FROM DOCUMENTED POLICIES AND PROCEDURES 32
11.2 NON-CONFORMING WORK 32
11.3 STOP WORK PROCEDURES 33

SECTION 12- IMPROVEMENT 33

SECTION 13 - CORRECTIVE ACTION 33

13.1 GENERAL PROCEDURE 34
13.1.1 Cause Analysis 34
13.1.2 Selection and Implementation of Corrective Actions 34
13.1.3 Monitoring of Corrective Action 35
13.2 ADDITIONAL AUDITS 35
13.3 TECHNICAL CORRECTIVE ACTION 35
13.4 DATA EVALUATION 35

SECTION 14 - PREVENTIVE ACTION 36

SECTION 15 - AUDITS 38

15.1 INTERNAL AUDITS 38
15.2 EXTERNAL AUDITS 39
15.2.1 Confidential Business Information (CBI) Considerations 39
15.3 PERFORMANCE AUDITS 39
15.4 SYSTEM AUDITS 39
15.5 HANDLING AUDIT FINDINGS 39

SECTION 16 - MANAGEMENT REVIEWS 40

16.1 MANAGEMENT REVIEW TOPICS 40
16.2 PROCEDURE 40

SECTION 17 - DATA INTEGRITY 41

17.1 ETHICS AND DATA INTEGRITY PROCEDURES 41
17.2 TRAINING 41
17.3 CONFIDENTIAL REPORTING OF ETHICS AND DATA INTEGRITY ISSUES 42
17.4 INVESTIGATIONS 42

SECTION 18 – PERSONNEL AND TRAINING 43

18.1 OVERVIEW 43
18.2 JOB DESCRIPTIONS 43
18.3 TRAINING 43
18.3.1 Ethical/Legal Responsibilities and Conflict of Interest 44
18.3.2 Training for New Staff 45
18.3.3 Ongoing Training 45
18.3.4 Education/Experience 46

SECTION 19 - IDOC & ADOC 49

19.1 INITIAL DEMONSTRATION OF CAPABILITY (IDOC) 49
19.2 ANNUAL DEMONSTRATION OF CAPABILITY (ADOC) 50

SECTION 20 - ACCOMODATIONS AND ENVIRONMENTAL CONDITIONS 50

20.1 ENVIRONMENTAL 50
20.2 WORK AREAS 51
20.3 FLOOR PLAN 51
20.4 BUILDING SECURITY 52

SECTION 21 - ENVIRONMENTAL METHODS AND METHOD VALIDATION 52

21.1 METHOD SELECTION 52
21.2 METHOD VALIDATION 53
21.3 ESTIMATION OF UNCERTAINTY OF MEASUREMENT 54
21.5 CONTROL CHARTS 54
21.6 CONTROL OF DATA 55
21.6.1 Computer and Electronic Data Requirements 56
21.6.2 Data Reduction 56
21.6.3 Data Review Procedures 57

SECTION 22 - CALIBRATION REQUIREMENTS: EQUIPMENT AND INSTRUMENTS 57

22.1 GENERAL EQUIPMENT REQUIREMENTS 57
22.2 SUPPORT EQUIPMENT 59
22.2.1 Support Equipment Maintenance 59
22.2.2 Support Equipment Calibration 59
22.3 ANALYTICAL EQUIPMENT 61
22.3.1 Maintenance for Analytical Equipment 61
22.4 INSTRUMENT CALIBRATION 61
22.4.1 Initial Instrument Calibration 61
22.4.2 Continuing Instrument Calibration 66
22.4.3 Unacceptable Continuing Instrument Calibration Verifications 67

SECTION 23 – STANDARDS AND REAGENTS 68

23.1 REFERENCE STANDARDS 68
23.2 STANDARDS AND REAGENTS 68
23.3 TRANSPORT AND STORAGE 69
23.4 LABELING 69
23.4.1 Stock Standards and Reagents 69
23.4.2 Prepared Standards and Reagents 70

SECTION 24 - COLLECTION OF SAMPLES 70

24.1 SAMPLING CONTAINERS AND KITS 71
24.2 SAMPLING PLAN 71

SECTION 25 – SAMPLE RECEIPT AND STORAGE 71

25.1 SAMPLE RECEIPT 71
25.1.1 Chain of Custody 71
25.1.2 Legal/Evidentiary Chain of Custody 72
25.2 SAMPLE ACCEPTANCE 72
25.2.1 Preservation Checks 72
25.3 SAMPLE IDENTIFICATION 72
25.4 SAMPLE ALIQUOTS / SUBSAMPLING 73
25.5 SAMPLE STORAGE 73
25.6 SAMPLE DISPOSAL 74
25.7 SAMPLE TRANSPORT 74

SECTION 26 - QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING 75

26.1 DEFINITIONS 75
26.2 ESSENTIAL QUALITY CONTROL PROCEDURES 76
26.3 INTERNAL QUALITY CONTROL PRACTICES 78
26.3.1 General Controls 78
26.4 PROFICIENCY TEST SAMPLES OR INTERLABORATORY COMPARISONS 84
26.4.1 Compliance to Accreditation Requirements 84
26.4.2 PT Sample Handling and Analysis 85
26.4.3 PT Reporting Procedure (TNI 2009 V1M2 Section 5.2) 85
26.5 DATA REVIEW 86
26.6 WATER QUALITY 86

SECTION 27 – REPORTING THE RESULTS 87

27.1 TEST REPORTS 87
27.2 SUPPLEMENTAL TEST REPORT INFORMATION 88
27.3 ENVIRONMENTAL TESTING OBTAINED FROM SUBCONTRACTORS 89
27.4 ELECTRONIC TRANSMISSION OF RESULTS 89
27.4.1 Electronic Data Deliverables (EDDs) 90
27.5 AMENDMENTS TO TEST REPORTS 90
27.6 ELECTRONIC SIGNATURES 90
27.7 REPORT SIGNATORIES 90

SECTION 28 - SAFETY 90

SECTION 29 - BIBLIOGRAPHY 91

Appendix A Ethics and Data Integrity Policy
Appendix B Organizational Charts
Appendix C Floor Plan
Appendix D Lab Certifications
Appendix E Data Qualifiers
Appendix F Equipment list

Section 1 - INTRODUCTION AND SCOPE

(TNI V1:M2 – Sections 1,2,3)

Teklab is an Environmental/Chemical testing laboratory. Consultants, landfills, municipalities, industry and state and federal government routinely use Teklab's services. A wide variety of analyses are performed on air, drinking water, aqueous samples, solid samples, and non-aqueous liquids in accordance with environmental regulations such as drinking water standards, NPDES permits, pre and post treatment standards, RCRA, UST/LUST standards and TCLP. Air Testing is a new service added in 2009.

This manual dictates Teklab's Quality Assurance Program. It is designed to ensure the precision, accuracy and completeness of all data generated for every client. This document describes the specific protocols which will be followed for sampling, sample handling and storage, chain of custody, and laboratory (and field) analysis. All Teklab, Inc. organizational units are subject to this manual.

Teklab, Inc. will protect Clients' confidential information and proprietary rights, as directed by local, state or federal laws. All confidential information and/or proprietary rights claimed by any Client and/or Vendor must be clearly identified in writing, prior to initiation of any business activity. Teklab, Inc. will voluntarily treat information generated by Teklab, Inc. (analytical results, sampling information, associated quality control results, etc.) as confidential in nature only without the fear of retribution. That is, Teklab, Inc. will not accept any liability for the inappropriate or accidental release of information, unless specifically agreed to under mutually binding contractual obligations. See Teklab, Inc. NELAP Policy Client Confidential Information for additional information and procedures.

All QA/QC procedures are in accordance with applicable professional technical standards, U.S. Environmental Protection Agency and Illinois Environmental Protection Agency requirements. Teklab uses only methods mandated by legal requirements, recognized published methods or methods developed and validated by Teklab. Methods are not used for reporting results unless competence for each particular matrix is demonstrated.

Chief Executive Officer — 12/15/17 Date — President — 12/15/17 Date

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(618) 344-1004

SIC Code 8734
Tax ID 37-1208950
CAGE Code OZZ46
CEC Number 02-695-3349

1.1 Teklab Inc

Teklab prominently displays its most recent TNI accreditation certificate in the customer service/sample reception area of the laboratory. The most recent NELAP accredited fields of testing are also available in Appendix D of this manual, on the Teklab server and on the company website (www.teklabinc.com). Any reports or general literature such as catalogs, advertising, business solicitations, proposals, quotations, or other materials that use the accrediting authorities name or the TNI/NELAP logo, do not imply endorsement by the accrediting authority and must be accompanied by at least the phrase "NELAP Accredited" and the laboratory accreditation number.

Teklab is a full service environmental/chemical-testing laboratory. Seven basic analytical departments exist: air (volatile and semi-volatile), volatile organic, semi-volatile organic, automated inorganic, wet chemistry, metals, and microbiology analysis. Semi-volatile and metals departments are further divided into instrumental and sample preparation. Volatile air analysis is performed at the Teklab Air Laboratory. See Quality Manual Appendix B for Teklab's Organizational Charts.

Technicians prepare samples for analysis and analysts perform the analysis. Due to personnel and fiscal restraints, Teklab personnel may operate as both technician and analyst.

The purpose of this Quality Manual is to outline the management system for Teklab Inc. The Teklab Inc Quality Manual defines the policies, procedures, and documentation that assure analytical services continually meet a defined standard of quality that is designed to provide clients with data of known and documented quality and, where applicable, demonstrate regulatory compliance.

This Quality Manual also sets the standard under which all laboratory operations are performed, including the laboratory's organization, objectives, and operating philosophy. It has been prepared to assure compliance with the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 **–** Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1-M1 through M7-ISO-2009). This Standard is consistent with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services and thus, the laboratory operates a quality system in conformance with ISO/IEC 17025:2005(E). In addition, the policies and procedures outlined are compliant with the various accreditation and certification programs listed in Appendix D.

1.2 Scope of Testing

The laboratory's scope of analytical testing services includes those listed in Appendix D – Laboratory Certifications.

1.3 Table of Contents, References and Appendices

The Table of Contents starts on Page 2 of this Quality Manual and the Appendices start after Section 29.

The Teklab Inc Quality Manual uses the references included in Modules 1-7 in the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis.

1.4 Acronyms

Quality control terms are generally defined within the Section that describes the activity.

1.4.1 Acronyms

A list of acronyms used in this document and their definitions are:

AB	-	Accreditation Body
ADOC	-	Annual Demonstration of Capability
CCB	-	continuing calibration blank
CCV	–	Continuing calibration verification
COC	–	Chain of custody
EPA	–	Environmental Protection Agency
FoPT	-	Fields of Proficiency Testing
g/L	–	grams per liter
GC/MS	–	gas chromatography/mass spectrometry
ICB	-	initial calibration blank
ICP	–	inductively coupled plasma
ICV	–	Initial calibration verification
IDOC	–	Initial Demonstration of Capability
LCS	–	Laboratory control sample
MBLK	-	Method Blank
MDL	–	method detection limit
mg/Kg	–	milligrams per kilogram
mg/L	–	milligrams per liter
MS	–	matrix spike
MSD	–	matrix spike duplicate
NELAP	–	National Environmental Laboratory Accreditation Program
NIST	–	National Institute of Standards and Technology
PQL	–	Practical Quantitation Limit
PT	–	Proficiency Test(ing)
PTOB	-	Proficiency Testing Oversight Body
PTPA	-	Proficiency Testing Provider Accreditor
QA	–	Quality Assurance
QC	–	Quality Control
RL	–	Reporting limit
RPD	–	Relative percent difference
RSD	–	Relative standard deviation
SOPs	–	Standard operating procedures
SQL -	-	Structured Query Language
std	–	standard
TNI	-	The NELAC Institute
ug/L	–	micrograms per liter

1.5 Management of the Quality Manual

The Quality Department is responsible for maintaining the currency of the Quality Manual.

The Quality Manual is reviewed at least annually by the Quality Department to ensure it reflects current practices and meets the requirements of any applicable regulations or client specifications. When sections of the manual are updated, the revision number is increased by one and the effective date is updated. The cover sheet and the first page of Section 1 of the Quality Manual must also be re-signed. To ensure consistency, the table of contents is updated whenever a Section is updated.

The Quality Manual is considered confidential within Teklab Inc and may not be altered in anyway except by approval of the Quality Department. If it is distributed to external users, it is for the purpose of reviewing Teklab Inc's management system and may not be used for any other purpose without written permission.

Section 2 - ORGANIZATION

(TNI V1:M2 – Section 4.1)

The laboratory is a legally identifiable organization. Teklab Inc's Tax ID number is noted in section 1 of this Quality Manual. The laboratory is responsible for carrying out testing activities that meet the requirements of the TNI Standard, the ISO/EIC 17025 Standard, and that meet the needs of the client. Through application of the policies and procedures outlined in this Section and throughout the Quality Manual:

- The laboratory ensures that it is impartial and that personnel are free from undue commercial, financial, or other undue pressures that might influence their technical judgment.
- Management and technical personnel have the authority and resources to carry out their duties and have procedures to identify and correct departures from the laboratory's management system.
- Personnel understand the relevance and importance of their duties as related to the maintenance of the laboratory's management system.
- Ethics and data integrity procedures ensure personnel do not engage in activities that diminish confidence in the laboratory's capabilities (see Appendix A, Section 3 "Management" and Section 17 "Data Integrity Investigations" for more information on data integrity).
- Confidentiality is maintained.
- The laboratory will report changes in ownership, significant personnel, laboratory name, or location to the accreditation authority within 30 days of occurrence.

2.1 Organization

Teklab Inc. is a full-service environmental commercial laboratory established in 1982. A variety of laboratory services are provided to serve industries specializing in air, drinking water, wastewater, sludge, soil, oil, and special waste testing. The following listed service centers are owned and operated by Teklab, Inc. Teklab operates in Collinsville, Illinois (Corporate Headquarters and Air Laboratory), Springfield, Illinois (Service center), Downers Grove, Illinois (Service center) and Lenexa, Kansas (Service Center).

Service Centers:

1. Springfield Service Center
   3920 Pintail Suite A
   Springfield, IL 62711
   (217)698-1004

The Springfield Service Center (SFSC) opened February 9th, 2009. The Springfield Service Center serves as a bottle order collection and sample drop off point for our clients in Central Illinois. This service center also has a sample courier service for bottle or air canister delivery and sample pick-up.

2. Kansas City Service Center
   8421 Nieman Road
   Lenexa, KS 66214
   (913)541-1998

The Kansas City/Lenexa Service Center opened its doors in the summer of 2007. The Kansas City Service Center serves as a bottle order collection and sample drop off point for our clients in Western Missouri and Eastern Kansas. This service center also has a sample courier service for bottle delivery and sample pick-up.

3. Downers Grove Service Center
   1319 Butterfield Road, Suite 502
   Downer's Grove, IL 60515
   (630)800-8639

The Chicago Area Service Center opened in July of 2015 and serves as a bottle order collection and sample drop off point for our clients throughout the Chicago Metropolitan Area

We are committed to providing the services our customers require, and as customer needs change, so will the analysis we perform.

The laboratory's organizational charts can be found in Appendix B of this Quality Manual. Additional information regarding responsibilities, authority and interrelationship of personnel who manage, perform or verify testing is included in Section 3 –"Management Roles and Responsibilities" and Section 18 – "Personnel and Training". These Sections also include

information on supervision, training, technical management, job descriptions, quality personnel, and appointment of deputies for key managerial personnel.

The laboratory has the resources and authority to operate a management system that is capable of identifying departures from that system and from procedures during testing, and initiates actions to minimize or prevent departures.

2.2 Conflict of Interest and Undue Pressure

Teklab is organized so that confidence in its independence of judgment and integrity are maintained at all times. It has processes to ensure that its personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work. Teklab has a proactive program for prevention and detection of improper, unethical or illegal actions.

All new employees are trained during orientation and all personnel are trained, at least annually, on data integrity, ethical behavior, legal responsibilities and conflict of interest. Each Teklab job description includes an agreement with the employee that they are aware of their ethical responsibilities and will avoid any conflict of interest. See Teklab Inc. NELAP Policy Ethics, Legal Responsibility, & Conflict of Interest for topics discussed during training.

Section 3 - MANAGEMENT

(TNI V1:M2 – Section 4.2)

The laboratory maintains a management system that is appropriate to the scope of its activities.

3.1 Management Requirements

Top management includes the CEO, President, Chief Financial Officer, Chief Marketing Officer, Laboratory Director, Technical Manager (however named), Quality Officers and Supervisors.

Management's commitment to good professional practice and to the quality of its products is defined in the Quality Policy statement in Section 3.3.

Management has overall responsibility for the technical operations and the authority needed to generate the required quality of laboratory operations. Management ensures communication within the organization to maintain an effective management system and to communicate the importance of meeting customer, statutory, and regulatory requirements. Management assures that the system documentation is known and available so that appropriate personnel can implement their part. When changes to the management system occur or are planned, managers ensure that the integrity of the system is maintained.

Management is responsible for carrying out testing activities that meet the requirements of the TNI Standard, the ISO/IEC 17025 Standard and the needs of the client.

Management implements, maintains, and improves the management system, and identifies noncompliance with the management system of procedures. Managers initiate actions to prevent or minimize noncompliance (See Section 12 "Improvement, Section 13 "Corrective Action and Section14 "Preventive Action").

Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised. See Section 18 "Personnel" for details on personnel requirements.

Management is responsible for defining the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and assuring that technical staff have demonstrated capability in their assigned tasks.

Training is kept up to date as described in Section 18 – "Personnel" by periodic review of training records and through employee performance review.

Management has specific responsibility for maintenance of the management system. This includes defining roles and responsibilities of personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation. The assignment of responsibilities, authorities, and interrelationships of the personnel who manage, perform, or verify work affecting the quality of environmental tests is documented in employee job descriptions and section 18 of this Quality Manual.

Management ensures that audit findings and corrective actions are completed within required time frames.

Designated deputies are appointed by management during the absence of the Technical Manager if the absence is for more than 15 days.

3.2 Management Roles and Responsibilities

3.2.1 Corporate: Chief Executive Officer / Chief Marketing Officer

3.2.1.1 Responsibilities

- Establishes current and long range goals, objectives, plans and policies.
- Plans, coordinates and controls the daily operation of the organization through organization's managers.
- Dispenses advice, guidance, direction and authorization to carry out major plans, standards and procedures, consistent with established policies.
- Meets with organization's other executives to ensure that operations are being executed in accordance with the organization's policies.
- Oversees the adequacy and soundness of the organization's financial structure.
- Plans and directs all investigations and negotiations pertaining to mergers, joint ventures, acquisition of businesses or the sale of major assets.

- Establishes and maintains an effective system of communication throughout the organization.
- Represents the organization with major customers, shareholders, the financial community and the public.
- Establishes strategic marketing plans to achieve corporate objectives for products and services.
- Develops, executes and directs comprehensive marketing plans and programs, both short and long range, to support sales and revenue objectives of the organization.
- Plans and oversees advertising and promotions activities.
- Designates, directs, advises and evaluates Teklab's sales staff.
- Works with Teklab's Project Management and Customer Service Departments to be a liaison for the customers, communicate customer needs and to develop and promote outstanding customer service.
- Establishes and maintains relationships with industry influencers and key community and strategic partners.

3.2.2 Corporate: Laboratory Director

The Laboratory Director provides the resources necessary to implement and maintain an effective quality and data integrity program.

3.2.2.1 Responsibilities

- Directs laboratory resources to accomplish company mission.
- Monitors standards of performance in quality control and quality assurance of laboratory practice.
- Monitors the validity of the analyses performed and data generated to assure reliable data.
- Directs laboratory in good automated lab practices.
- Directs production standards of laboratory
- Works with the IT department regarding all aspects of Teklab's Laboratory Information Management System.
- Responsible for an in depth understanding of methodology and regulatory requirements.
- Works with the Technical Manager to coordinate method development, solve LIMS related issues, interpret test results and troubleshoot analytical/instrumentation issues.
- Provides technical assistance to laboratory personnel.
- Ensures availability of laboratory resources.
- Involved with instrument optimization and maintenance.
- When absent for a period of time exceeding 15 consecutive calendar days, the President will temporarily perform this function.

3.2.3 Corporate: President/Chief Financial Officer

3.2.3.1 Responsibilities

- Establishes current and long range goals, objectives, plans and policies, subject to approval by the Board of Directors.
- Manages the operations of the laboratory through subordinate managers to ensure that the current and long range goals, objectives, plans and policies are met in a financially responsible manner.
- Dispenses advice, guidance, direction, and authorization to carry out major plans, standards and procedures, consistent with established policies and Board approval.
- Oversees the adequacy and soundness of the organization's financial structure.
- Determines agencies and suppliers of record, and negotiates contract terms and conditions for major services and suppliers.
- Directs company finance and purchasing.
- Represents the organization with major customers, shareholders, the financial community and the public.
- Designates, directs, advises and evaluates the laboratory Supervisors to achieve timely data reporting, while maintaining high safety and quality standards.
- Assists in the planning and implantation of safety policies and procedures in compliance with local, state and federal Occupational Safety and Health Administration (OSHA) rules and regulations.
- Directs, advises and coordinates personnel in their role in the analytical and operational activities of the laboratory to safely produce high quality data as quickly as possible.
- Identifies, analyzes and resolves, and/or assists personnel in solving operational problems.
- Ensures that laboratory resources are available.
- Handles difficult or highly technical situations with clients as needed.
- When absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director will temporarily perform this function.
- If this absence exceeds 35 consecutive calendar days, the primary accreditation body shall be notified in writing.

3.2.4 Corporate: Technical Manager

3.2.4.1 Responsibilities

- Responsible for standards of performance in quality control/quality assurance, the validity of the methodologies and technologies of the analyses performed and the data generated in the laboratory to assure reliable data
- Provides technical assistance to laboratory personnel
- Oversees Teklab's QA/QC program to maintain quality assurance following TNI quality systems requirements. Some of these functions include, but are not limited to, quality control, document control, accreditations, audits, data integrity, data validation and report review.

- Oversees Teklab's Training program.
- Responsible for in depth understanding of methodology and regulatory requirements.
- Oversees method research, development, reviews, implementation and updates. Responsible for implementing and approving standard operating procedures as related to methods.
- Involved with instrument optimization and maintenance.
- When absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director will temporarily perform this function.
- If this absence exceeds 35 consecutive calendar days, the primary accreditation body shall be notified in writing.

The Technical Manager (however named) or designee:

1. is not the technical manager of more than one accredited environmental laboratory.
2. is a full-time laboratory staff member and supervises laboratory operations and data reporting.
3. meets the general and education requirements and qualifications found in Sections 4.1.7.2 and 5.2.6.1 of the TNI Standard - EL-V1M2-2009.

The Technical Manager's proof of experience in the fields of accreditation may be found on the Teklab Server in Employees Electronic Training File.

3.2.5 Corporate: Quality Officer

The Quality Officer (or designee) is responsible for the oversight and review of quality control data, and is independent from laboratory operations. The Quality Officer's training and proof of experience in QA/QC procedures, knowledge of analytical methods, and the laboratory's management system are available in employee training record files, which are stored on the Teklab Inc server.

3.2.5.1 Responsibilities

- Perform and maintain Certificate/Accreditation functions
- Provide QA/QC expertise to staff and supervisors
- Supervise and/or maintain performance testing program
- Supervise and /or prepare and maintain Quality Manual
- Notify laboratory supervisors of quality system deficiencies and monitor Corrective actions
- Supervise and/or perform test data validation and data entry
- Supervise and/or perform Level 2, 3 and Level 4 quality control data review
- Responsible for in depth understanding of methodology and regulatory requirements
- Approve and/or prepare laboratory Standard Operating Procedures
- Perform internal QA/QC audits
- Respond to corrective actions from both internal and external audits
- Supervise and/or maintain method related QA/QC documentation according to the 2009 TNI standard
- Perform Quality Assurance Unit (QAU) duties as defined in GALP

- Supervise and/or maintain document control and data archiving

3.2.6 Corporate: Director of Customer Service

3.2.6.1 Responsibilities

- Responsible for designating and supervising project managers and customer service specialists
- Provides initial and ongoing orientation, safety and quality training of direct reports
- Analyzes and resolves, or assists workers in resolving customer service problems
- Establishes or adjusts department work procedures to meeting testing schedules
- Identifies and either provides on the job training or seeks training opportunities to ensure that project management and customer service quality meets TNI standards
- Confers with Laboratory Supervisors to achieve timely data reporting to clients, while maintaining the high safety and quality standards
- Confers with the Chief Marketing Officer on customer service and project related needs or issues and to keep abreast of the status of future and potential workload

3.2.7 Collinsville Air laboratory: Director of Operations/Analyst

3.2.7.1 Responsibilities

- Responsible for standards of performance in quality control/quality assurance, the validity of the methodologies and technologies of the analyses performed and the data generated in the laboratory to assure reliable data.
- Designates, directs, advises and evaluates Teklab's QA/QC program to maintain quality assurance following TNI quality systems requirements. Some of these functions include, but are not limited to, quality control, data integrity, data validation and report review.
- Responsible for in depth understanding of methodology and regulatory requirements.
- Oversees method research, development, reviews, implementation and updates. Responsible for implementing and approving standard operating procedures as related to methods.
- Involved with instrument optimization and maintenance.
- Provide QA/QC expertise to staff
- Maintain method related QA/QC documentation according to the 2009 TNI standard
- Identifies, analyzes and resolves, and/or assists personnel in solving operational problems.
- Ensures that laboratory resources are available.
- Handles difficult or highly technical situations with clients as needed.

- When absent for a period of time exceeding 15 consecutive calendar days, the Corporate Laboratory Director or the President will temporarily perform this function.
- If his/her absence exceeds 35 consecutive calendar days, the primary accreditation body shall be notified in writing.

3.3 Quality Policy

Management's commitment to quality and to the management system is stated in the Quality Policy below, which is upheld through the application of related policies and procedures described in the laboratory's Quality Manual, SOPs and policies.

Teklab's Management is committed to ensuring compliance with the TNI Standard and shall strive to continually improve the effectiveness of the Management System. Teklab's overall Quality objective is adhere to good professional practices and to develop and implement procedures for field sampling, chain of custody, laboratory analysis and reporting, that will provide results that are legally defensible in a court of law. Specific procedures for sampling, chain of custody, laboratory instrument calibration, laboratory analysis, reporting of data, internal quality control, audits, preventive maintenance of equipment and corrective actions are described in the applicable 1000 series SOPs and other sections of this manual. The purpose of this section is to address the overall objectives that produce accurate, precise, complete, representative and comparable data. The Teklab QA/QC program is communicated and monitored by Teklab's Quality Department.

The Teklab QA/QC program must provide technicians, analysts, and managers with the direction and information necessary to consistently produce reliable and valid analytical data. These results are best attained by rigorously following the validated standard operating procedures and this Quality Manual. This Quality Manual has been developed by Teklab and is available to each Department in an electronic format.

SOP reading is completed at least annually. New laboratory employees are required to read method SOPs once per quarter for six quarters. SOP reading is tracked using controlled reading forms or in controlled Department databases. Employees note the revision and date read for each SOP. Documentation of reading provides evidence that employees have read, understood, and are using the latest version of Teklab Inc. SOPs.

New employees will read the Teklab Quality Manual in their first year of employment. Other laboratory personnel will read the Quality manual when a revision is made.

Teklab provides all employees with on-the-job training specific to their job assignment. Safety, Quality and Ethics training are provided upon hiring and in ongoing programs. Every Teklab employee must ensure that the generation and reporting of quality analytical data is a fundamental priority. All employees are trained annually on ethical principles and procedures surrounding the data that is generated. The laboratory maintains a strict policy of client confidentiality. Off site training is provided on an as needed basis. The following is a partial listing of the types of training provided by Teklab:

- Safety
- Technical training specific to job assignment
- Data Integrity, Ethics and Conflict of Interest
- NELAP quality systems

3.4 Ethics and Data Integrity System

The laboratory has an Ethics and Data Integrity policy that is included in Appendix A. The laboratory's Ethics and Data Integrity program, training and investigations are discussed in Section 17 – "Data Integrity Investigations". Slides of Teklab's Data Integrity Training can be found in the Quality Documents folder on the Teklab Server.

3.5 Documentation of Management/Quality System

The management system is defined through the policies and procedures provided in this Quality Manual and written laboratory Standard Operating Procedures (SOPs) and policies.

3.5.1 Quality Manual (TNI 2009 V1M2 4.2.8.3)

The Quality Manual contains the following required items:

3.5.1.1 document title;

3.5.1.2 laboratory's full name and address;

3.5.1.3 name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;

3.5.1.4 identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;

3.5.1.5 identification of the laboratory's approved signatories;

3.5.1.6 the signed and dated concurrence (with appropriate names and titles), of all responsible parties including the quality Officer(s), technical Manager(s), and the laboratory director;

3.5.1.7 the objectives of the management system and contain or reference the laboratory's policies and procedures;

3.5.1.8 the laboratory's official quality policy statement, which shall include management system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and

3.5.1.9 a table of contents, and applicable lists of references, glossaries and appendices.

This Quality Manual contains or references all required elements as defined by the TNI Standard - V1:M2, Section 4.2.8.4.

3.5.2 Standard Operating Procedures (SOPs)

The laboratory has documented procedures for making and controlling revisions to SOPs. The following information is included on each page of the SOPs:

- SOP number;
- Revision date;
- Revision letter;
- Current page number and total pages of a section.

The effective date of the SOP is the date the SOP is signed by a Quality Officer or other approving authority. Standard operating procedures (SOPs) represent all phases of current laboratory operations and are available to all personnel. They contain sufficient detail to allow someone with similar qualifications to perform the procedures. There are two types of SOPs used in the laboratory:

1) test method SOPs, which have specific requirements as outlined below
2) general use SOPs which document general procedures.

See SOP1010 for more information on SOPs.

Each accredited analyte or method has an SOP. Sometimes an SOP is a copy of a method, and any additions are clearly described. The laboratory's test method SOPs are listed in SOP1010. SOPs should contain or reference the following information where applicable.

i. identification of the method;
ii. applicable matrix or matrices;
iii. limits of detection and quantitation;
iv. scope and application, including parameters to be analyzed;
v. summary of the method;
vi. definitions;
vii. interferences;
viii. safety;
ix. equipment and supplies;
x. reagents and standards;
xi. sample collection, preservation, shipment and storage;
xii. quality control;
xiii. calibration and standardization;
xiv. procedure;
xv. data analysis and calculations;
xvi. method performance;
xvii. pollution prevention;
xviii. data assessment and acceptance criteria for quality control measures;
xix. corrective actions for out-of-control data;
xx. contingencies for handling out-of-control or unacceptable data;
xxi. waste management;
xxii. references; and
xxiii. any tables, diagrams, flowcharts and validation data.

3.5.3 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is based upon whichever policy the most strict (if applicable); otherwise the order is as follows:

- Quality Manual
- SOPS
- Reference Methods
- Policies

Section 4 - DOCUMENT CONTROL

(TNI V1:M2 – Section 4.3)

A controlled document is one that is uniquely identified, issued, tracked, and kept current as part of the management system.

An approved document is one that has been reviewed, and either signed and dated, or acknowledged in writing or by secure electronic means by the issuing authority (ies).

Retired documents are documents that have been superseded by more recent versions or are no longer needed.

Documents can be "SOPs, policy statements, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written." (TNI 2009 V1M2 4.3.1). See section 5 for information on control of records.

Procedures for document control and management include controlling, distributing, reviewing, and accepting modifications. The purpose of document control is to preclude the use of invalid and/or obsolete documents.

4.1 Controlled Documents

Documents are reviewed at least annually to ensure their contents are suitable and in compliance with the current management system requirements, and accurately describe current procedures.

Approved copies of documents are available to staff at all locations where operations are essential to the effective functions of the laboratory. Superseded or obsolete paper and electronic documents must be promptly removed from all points of issue and archived following the procedures in SOP 1291. SOPs are located on the Teklab Inc server in the Quality Documents folder. A copy of the current SOP for any analysis is in the appropriate laboratory section performing that analysis. The Quality Department maintains the original Microsoft Word copy of the most current SOP revision and retired revisions of all SOPs.

Controlled internal documents are uniquely identified with :

1) revision date
2) revision letter

Plus the following for SOPs and the Teklab Quality Manual:

3) unique identification (text or number)
4) page number
5) the total number of pages (or a mark to indicate the end of the document)
6) the signatures of the approving authority

SOPs and the Teklab QAM are reviewed annually. To comply with KEDP and ODEQ requirements, the review date of method SOPs is noted on the PDF copy of each. A review date is not required when an SOP is revised in the same year. Review dates are tracked in the Training Database located in the Quality folder on the Teklab Server.

SOPs may be prepared by anyone at Teklab, Inc. All SOPs are prepared in a standard layout containing the same sections (See SOP1010). Documents must be reviewed, revised (as appropriate) and approved for use prior to issue by an "approving authority" which is one of the following staff - Quality Officer, Laboratory Management or Laboratory Supervisor. See SOP 1010 "SOPs and Controlled Documents" for guidelines. Where a laboratory's quality manual contains the necessary requirements, a separate SOP or policy is not required.

A master list of SOPs, which includes SOP number, SOP title, revision and review dates is maintained by the Quality Department and is updated each time a revision is made to an SOP or an SOP is reviewed. The master list is stored in the Quality Department's Training Database, located on the Teklab Inc server. The Controlled Document database, located on the Teklab server, tracks QA manual and other controlled document revisions and can be modified to track any controlled document when required.

The current QA manual is accessible to laboratory personnel via the Quality Documents folder on the Teklab Inc server.

Photocopies of controlled documents or reprints of electronic documents made out with the QA Department are not controlled. As such, it is the responsibility of the document holder to ensure that they have the most current revision.

4.1.1 Changes to Controlled Documents

4.1.1.1 Paper Document Changes

Document changes are approved by an approving authority (Section 4.1 lists approving authorities). Modifications to paper documents that require a revision change shall be clearly written on the document and given to the Quality Department for review. Once the review is complete, the document can be approved and signed by an approving authority. The document will then be processed by the Quality Department and issued to the relevant departments.

Changes that are not process modifications but clarifications (also called minor revisions) may be performed without changing the revision letter of the document. The Quality department shall be notified of any minor revisions. The modified document shall then copied and distributed to the applicable department/s, and obsolete documents shall be removed from all points off use and noted as such in the master list of controlled

documents. Minor amendments/modifications to documents are incorporated into a new revision and reissued when the document is reviewed and updated on or before its scheduled review cycle.

A reason for the minor modification or change is written on the document itself and is provided as historical information. This is not required if the reason for the modification is evident (e.g. to correct a spelling error).

4.1.1.2 Electronic Document Changes

A Microsoft Word copy of the document (if available) may be requested from the Quality Department. The document will be emailed to the reviewer and should be downloaded to the C Drive of their personal computer before making any changes. All editing must be tracked following the guidelines in SOP 1010. The final document must then be emailed back to the Quality Department. Revised 1000 series SOPs are reviewed by the Quality Department and Method SOPs are reviewed by technical reviewers; such as the Technical Manager or the Quality Training Officer. Once the document has passed review, it can be approved and signed by an approving authority. When signed, the document will then be processed by the Quality Department and issued to the relevant areas of the laboratory.

Intermediate revisions can be made directly into PDF copies of SOPs or the Quality Manual located in the Quality Documents folder. These revisions must be approved by either the Department Supervisor or a member of the Quality Department.

Changes to documents are processed following the guidelines in SOP 1010.

4.2 Obsolete Documents

All invalid or obsolete documents are removed from general distribution, or otherwise prevented from unintended use. The master copy of an obsolete document is marked with the word “retired”, a retired date and is archived in accordance with SOP 1291 “Record Retention and Access”. Archived documents may be in paper or electronic format. All copies of obsolete documents must be removed from point of use and destroyed. Documents must be securely stored for at least five years before being destroyed. If documents have been scanned and stored on the Teklab Inc Server, related hard copies can be destroyed at the discretion of the applicable department. Storage boxes are maintained in the Teklab storage area until archived to an off-site storage facility. Both the on-site and off-site storage areas have all access documented in an access log maintained at the respective sites. Both storage facilities are protected against fire, theft, loss, environmental deterioration, and vermin. Electronic records are protected from electronic or magnetic sources in a fire proof safe. Details of all stored (and labeled) storage boxes (current and destroyed) are recorded in a Microsoft Access Database by the Quality Department for tracking purposes. Controlled electronic documents are stored on the Teklab server indefinitely (where applicable). The Teklab server is backed up on a daily basis. Two Iomega storage units, that can be located via the Teklab Inc network, are also available to archive documentation. Each has a built in raid configuration to provide data redundancy.

Note: See section 5 of this QA manual for specific guidelines on the control and archival of laboratory records.

In the event that the laboratory goes out of business, documents will be maintained at the off-site storage facility until they can be securely destroyed. If the laboratory transfers ownership, records and documentation shall be transferred to the new ownership. In the event the laboratory transfers geographic location, records and documentation shall be maintained at the off-site storage facility until the records can be securely destroyed.

Section 5 - CONTROL OF RECORDS

(TNI V1:M2 – Section 4.13)

Records may be on any form of media, including electronic and hard copy. Records allow for the historical reconstruction of laboratory activities related to sample-handling and analysis. See Section 4 for information on control of documents.

5.1 Records Maintained

The laboratory maintains a record keeping system that facilitates the retrieval of working files and archived records for inspection and verification purposes by the NELAP accrediting authority.

The laboratory documents and maintains records related to all procedures and activities to which a sample is subjected, including:

a) Identity of personnel involved in sampling, preparation and testing;

b) Sample preservation, including but not limited to: sample container and compliance with holding times;

c) Sample identification code, receipt, log-in, acceptance or rejection;

d) Sample storage and tracking, including: shipping receipts, transmittal form, and internal routing and assignment records;

e) Sample preparation including: cleanup and separation procedures, extract or digestate identification codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

f) Sample analysis;

g) Standard and reagent origin, receipt, preparation and use;

h) Equipment receipt, use specification, operating conditions and preventative maintenance

i) Calibration criteria, frequency and acceptance criteria

j) Method performance criteria including quality control requirements

k) Quality control protocols and assessment;

l) All automated sample handling systems;

m) Calculations and statistical formulae used by the laboratory,

n) written procedures for all calculations are available for review;

o) representative calculations are available and indicate that routine calculations are consistent with the written procedures;

p) all raw data and supporting information needed to recreate calculations are available for review;

q) the appropriate number of significant figures are carried out through all recorded data and calculations; and

r) the least precise step is identified in the calculations and the number of significant figures is an accurate reflection of the actual tolerances of the instrument or equipment used in this step.

s) Procedures to verify that the reported data is free from transcription and calculation errors;

t) Data handling, including but not limited to: reduction, review, confirmation, interpretation, assessment or validation, and reporting;

u) QC measurements, including procedures to select samples on which to perform QC measurements, and assessment of method performance;

v) Requirements specified in sample acceptance and receipt section of this manual;

w) Electronic records, including but not limited to; copies of final reports, PT studies, bench sheets, instrument strip charts or printouts, data calculations, and data reports for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records include an input summary and copy of the PT study final reports from the PT vendor used by the laboratory;

x) Data review and cross-checking forms

y) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with the sample receipt, preparation, analysis and reporting; and

z) Procedures that maintain an unequivocal link with the unique field identification and the laboratory identification code assigned each sample.

5.2 Records Management and Storage

The laboratory maintains a record management system for control of laboratory records. See SOP# 1010, 1060, 1290 and 1291 for more information on tracking, reporting and storage.

Data is recorded immediately and legibly in permanent ink (data generated by automated data collections systems is recorded electronically.) Corrections are initialed and dated with the reason noted for corrections other than transcription errors. A single line strikeout is used to make corrections so that the original record is not obliterated.

Excel data sheets used for data entry in the laboratory are coded to allow tracking and automatic documentation of all changes made within that file. The worksheet containing the tracking information is stored within the workbook for the life of the file.

Electronic corrections in LIMS are tracked via SQL files which log all changes made. SQL files are retained securely on the Teklab server for at least 5 years.

Teklab servers are backed up daily Monday to Friday, with the exception of the website server, which is backed up when changes are made to the website. A backup of all servers is maintained onsite and at a remote data center. All offsite backups are encrypted using 256 bit AES. The key is stored at our MSP. The SQL database is backed up incrementally every hour except for a maintenance window from 1:30am to 6:00am at which time a full backup is run.

Where computers or automated equipment is used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory:

- Maintains computer and automated equipment to ensure proper functioning and provide environmental and operating conditions necessary to maintain the integrity of calibration and test data
- Performs software and hardware testing
- Establishes and implements procedures for the maintenance of security of data, including the prevention of unauthorized access to, and the unauthorized amendment of, computer records and
- Maintains hard copy or write protected backup copies of records that are stored or generated by computers.

The laboratory controls access to all programs that are used to acquire, process, record or report data. All programs have limited access and are dependent on the security permissions that are assigned to each employee. An employee is granted access depending on his/her responsibilities and job description.

Records, including electronic records, are easy to retrieve, legible, and protected from deterioration or damage; held secure and in confidence; and are available to accrediting bodies for a minimum of five years or as required by regulation or contract. Records that are stored only on electronic media are supported by the hardware and software necessary

for their retrieval. Access to protected records is limited to applicable department personnel. Procedures for identification, access, filing, storage, maintenance and disposal of quality and technical records can be found in SOPs 1010, 1060 and 1291. Quality records shall include reports from internal audits as well as records of corrective and preventive actions.

The laboratory maintains the record management system for control of all applicable information, in an organized, chronological order. Hard copy records are segregated by type (i.e. laboratory data packets, Teklab Reports etc.), in chronological order, and placed in storage boxes. The exterior of the storage box indicates the contents. Storage boxes are maintained in the Teklab storage area until archived to an off-site storage facility. Additional information regarding control of data is included in Section 21.5 – "Control of Data".

Paper records must be safely stored, held secure, and in confidence to the client. All information necessary for the historical reconstruction of the data must be maintained. Non-drinking water records must be retained for 5 years from generation of last entry in records. Drinking water chemical analysis records from public water systems serving at least 25 persons or having at least 15 service connections must be maintained for 10 years from the generation of the last entry in the records. Lead and copper drinking water records for must be maintained for 12 years from generation of last entry. Per Louisiana regulations all air analysis records must be kept for at least 10 years. Records may be stored longer at client request.

Metals and Inorganics data is scanned and kept on the server per the regulation retention times noted above. Hard copies of scanned Metals and Inorganics data are kept for one year. VOA and Organics data is electronically generated and is stored on the Teklab Server for at least five years.

Data for all other environmental analyses that are associated with the laboratory's accreditation is stored for a minimum of five years, unless otherwise specified in another regulation. Pertaining to all suppliers from whom it obtains support services or supplies required for test, for a minimum of five years.

In the event that the laboratory transfers ownership or goes out of business, records are maintained or transferred according to client instructions. Appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

5.3 Legal Chain of Custody Records

Evidentiary sample data are used as legal evidence. Procedures for evidentiary samples are outlined below and can also be found in SOP1065.

The laboratory establishes and maintains the following basic requirements for evidentiary chain-of-custody:

- The evidentiary chain-of-custody records accounting for an unbroken possession of the sample while it is in the laboratory's custody.

- The evidentiary chain-of-custody records include signatures of all individuals who were involved with physically handling the samples and the time of day and calendar date that the sample was physically transferred from one individual to the next individual or to and from a controlled access storage area. A sample is considered to be in someone's custody only if it is in one's actual physical possession, if it is in one's view, after being in one's physical possession, or if it is kept in a secured area restricted to authorized personnel only.
- A minimum number of persons shall be involved in sample handling.
- The laboratory limits the number of documents that are required to establish evidentiary chain-of-custody.
- The evidentiary chain-of-custody forms remain with the samples during transport or shipment.
- The laboratory controls access to all evidentiary samples and sub-samples, and documents this control as described in the Sample Acceptance and Receipt section of this manual.
- Transfer of samples, sub-samples, digestates or extracts to another laboratory is subject to all of the requirements for evidentiary chain-of-custody.
- The laboratory ensures that sample containers that are shipped, are sealed in such a manner so that tampering by unauthorized personnel is immediately evident. If any seals are not intact, the laboratory notes this on the chain-of custody.
- The laboratory ensures that, if required, individual sample containers are sealed in such a way as to prevent tampering.
- The laboratory maintains records of sample disposal practices including, where appropriate, the date of sample or sub-sample disposal and the name of the responsible person.
- The disposal of the physical sample occurs only with the concurrence of the affected legal authority, sample data user and submitter of the sample.
- The laboratory documents and retains a record of all conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample.
- The sample records indicate the date of disposal, the nature of disposal (such as depleted, sample manifested to a hazardous waste facility, sample returned to client), and the identity of the individual who performed the task.
- The laboratory has waste collection, storage, recycling, and disposal procedures and policies as part of their SOPs. Where disposal practices are included as part of an approved test method, the laboratory strictly follows the approved test method's disposal practices. While more specific disposal criteria are not an aspect of this manual, the laboratory applies appropriate Federal, state, and local disposal practices as a part of good laboratory practices.

Section 6 – REVIEW OF REQUESTS, TENDERS AND CONTRACTS

(TNI V1:M2 – Section 4.4)

The review of all new work assures that requirements are clearly defined, the laboratory has adequate resources and capability, and the test method is applicable to the customer's needs. This

process ensures that all work will be given adequate attention and avoid shortcuts that may compromise data quality.

Contracts for new work may be formal bids, signed documents; verbal, or electronic. The client's requirements, including the methods to be used, must be clearly defined, documented and understood. The review must also cover any work that will be subcontracted by the laboratory.

See SOP1015 for details on Review of Requests, Tenders and Contracts and SOP 1100 for Subcontracting guidelines.

Section 7 - PURCHASING SERVICES AND SUPPLIES

(TNI V1:M2 – Section 4.6)

The laboratory ensures that purchased supplies and services that affect the quality of environmental tests are of the required quality by using approved suppliers and products.

7.1 Procedure for Purchasing

Supplies and Services that affect the quality of environmental tests are purchased by the Chief Financial Officer, who also reviews and approves the suppliers of services and supplies.

Purchase orders are automatically assigned unique order numbers and are generated from the LIMS. The Vendor section of the LIMS contains information that adequately describes the services and supplies ordered. Order details are stored under each vendor/supplier and allows for tracking and evaluation of past purchases.

Clipboards with Supply Order Forms are available in all departments of the laboratory. The form contains information such as the department, date (the date the item was added to the form), a description of the item and a priority code. Priority codes run from 1 (need immediately) to 3 (order within the next 2 weeks). Priority code 4 is reserved for special request/new items. When an item is ordered, the order date is noted beside the applicable item. A copy of the form is then given to the Customer Service department. When the goods are delivered to Teklab, the Customer Service department can use the Supply Order Form to expedite the distribution of supplies to the relevant departments. The laboratory strives to maintain an adequate supply of critical items to ensure continued analysis without interruption.

Purchased supplies that affect the quality of tests are inspected for breakage, leaks or any other damage when received. The supplies are stored according to manufacturer's recommendations, laboratory SOPs or test method specifications. See SOP1260 for information on supply receipt procedures.

Copies of calibration documentation (e.g. weight calibrations, NIST thermometer calibrations, balance maintenance/calibrations) are kept on file by the Quality Department. Certificate of Analysis details are logged into the LIMS. A copy of the certificate is scanned and linked to information in the LIMS by the relevant department or a member of the

Quality Department. See Section 23 "Reagents and Standards" and SOP1250 for more information.

7.2 Approval of Suppliers

The Chief Financial Officer maintains a list of approved suppliers in the Teklab LIMS. Vendors that are no longer used are inactivated through the same system.

Evaluation Procedure
Evaluation and selection of suppliers/ vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products/services, the quality of their service, their past history and competitive pricing. To ensure that critical consumables and equipment conform to specified requirements, all purchases from specific vendors are approved by a member of the management staff.

If problems with supplies (or services) arise after the product has entered the laboratory, the deficiency information can be relayed by the relevant department directly to the Chief Financial Officer or via Teklab's weekly management meetings. Critical deficiencies (that impact safety or the quality of data) must be relayed to the Chief Financial Officer as soon as possible. All returns are dealt with on a case by case basis.

Section 8 - SUBCONTRACTING OF ENVIRONMENTAL TESTS

(TNI V1:M2 – Section 4.5)

8.1 Procedure

When Teklab must subcontract analysis due to workload, need for further expertise, temporary incapacity, or on a continuing basis, work is placed with a laboratory accredited under NELAP for the test to be performed or with a laboratory that meets the applicable statutory and regulatory requirements for performing the tests and submitting the results of test performed. All subcontracted analyses and the name of the subcontracted laboratory are documented in the case narrative of the final report. Any non-NELAP accredited work does not have the letters "NELAP" in the qualifier column. The intent to subcontract analysis is specified in the project quote when Teklab intends to subcontract any part of a project. When possible, Teklab will advise the client in writing of any subcontracted analysis. Teklab maintains a register of all subcontractors that it uses for environmental tests and a record of the evidence of compliance for each. A record of subcontracted analysis is retained at Teklab and is archived in accordance with this manual. Teklab will ensure that the subcontract laboratory is provided all necessary information to meet the same commitments made to the client by the primary laboratory.

See SOP1100 for Subcontracting procedures and guidelines and SOP 1015 for review of requests, tenders and contracts.

Section 9 - SERVICE TO THE CLIENT

(TNI V1:M2 – Section 4.7)

The laboratory collaborates with clients and/or their representatives in clarifying their requests and in monitoring laboratory performance related to their work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply with the request within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other clients.

9.1 Client Confidentiality

Teklab Inc's confidentiality policy is to not divulge or release any information to a third party without proper authorization. Third party requests for data and information are referred to the client. Data and records identified as proprietary, privileged, or confidential are exempt from disclosure.

All electronic data (storage or transmissions) are kept confidential, based on technology and laboratory limitations, as required by client or regulation.

Teklab, Inc. will protect Clients' confidential information and proprietary rights, as directed by local, state or federal laws. All confidential information and/or proprietary rights claimed by any Client and/or Vendor must be clearly identified in writing, prior to initiation of any business activity. Teklab, Inc. will voluntarily treat information generated by Teklab, Inc. (analytical results, sampling information, associated quality control results, etc.) as confidential in nature only without the fear of retribution. That is, Teklab, Inc. will not accept any liability for the inappropriate or accidental release of information, unless specifically agreed to under mutually binding contractual obligations. See Teklab, Inc. NELAP Policy Client Confidential Information for additional information and procedures.

Teklab quality training includes training on procedures for protecting clients' confidential information. Clients' names or client's sample identifications are not listed in any laboratory data packets. Information in the laboratory data packets is identified with Teklab generated laboratory identifications only. Printed records containing client information are shredded before disposal. See Teklab Inc. NELAP Policy Client Confidential Information for policy and procedural details discussed during training.

9.2 Client Support

Communication with the client, or their representative, is maintained to provide proper instruction and modification for testing. Technical staff are available to discuss any technical questions or concerns the client may have.

The client, or their representative, may be provided reasonable access to laboratory areas to witness testing.

Delays or major deviations to testing are communicated to the client immediately, where possible, by email or phone by the applicable Project Manager, a member of the Customer Service Team or the Chief Marketing Officer.
Teklab will provide the client with all requested information pertaining to the analysis of their samples.

9.3 Client Feedback

The laboratory seeks both negative and positive feedback following the completion of projects and/or periodically for ongoing projects. Feedback provides acknowledgement, corrective actions where necessary, and opportunities for continuous improvement.
Methods of receiving feedback may include conversations with customers (phone or email), website and email questionnaires.

Negative customer feedback is documented as a customer complaint (see Section 10 – "Complaints").

Section 10 - COMPLAINTS

(TNI V1:M2 – Section 4.8)

The purpose of this section is to ensure that customer complaints are addressed and corrected, and done so in a timely manner. This includes requests to verify results or analytical data. Complaints provide the laboratory an opportunity to not only improve client satisfaction but also laboratory operations.

Customer complaints are dealt with on a case by case basis. All customer complaints are documented by the person receiving the complaint and addressed to the responsible manager. Complaints concerning areas such as turnaround time or pricing, are handled solely at the discretion of Teklab management. The Technical Manager, Quality Officer or Teklab Management handle all QA/QC complaints. An investigation determines the validity of the complaint. If it is determined that the complaint has merit, the procedures outlined in Section 13 – Corrective Action are utilized. If it is determined that a complaint is without merit, it is documented, and the client is contacted by the appropriate Project Manager.

A complaint such as a concern that data is repeatedly late should be reviewed for preventive action (see Section 14 – "Preventive Action") to minimize a future occurrence.

The laboratory has a documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities.
The laboratory audits the laboratory activities as required in this manual resulting from a complaint, or any other circumstance that impacts the laboratory's compliance with:

1. The laboratory's policies and procedures;

2. The requirements of this manual; and

3. The quality of the laboratory's tests.

The laboratory documents and maintain records of the complaint/s, the laboratory's subsequent actions, and any corrective actions and/or revised reports.

Section 11 - CONTROL OF NON-CONFORMING ENVIRONMENTAL TESTING WORK

(TNI V1:M2 – Section 4.9)

Non-conforming work is work that does not meet acceptance criteria or requirements. Non-conformances can include departures from standard operating procedures, test methods or unacceptable quality control results (see Section 26 – "Quality Assurance for Environmental Testing"). Identification of non-conforming work can come via customer complaints, quality control, instrument calibration, evaluating consumable materials, staff observation, final report review, management reviews and internal and external audits.

11.1 Exceptionally Permitting Departures from Documented Policies and Procedures

Requests for departures from laboratory procedures are approved by the Technical Manager or his/her designee and documented on a case by case basis with the applicable analytical data or final report. Planned departures from procedures or policies do not require audits or investigations.

If a client requests a departure from laboratory procedures, the laboratory does not have to consider that departure as a nonconformance that requires corrective action. However, that nonconformance must be documented as a nonconformance (or however named) that was approved by management.

11.2 Non-Conforming Work

The laboratory policy for control of non-conforming work is to identify the non-conformance and take appropriate action. All employees have the authority to stop work on samples when any aspect of the process does not conform to laboratory requirements.

The responsibilities and authorities for the management of non-conforming work are detailed in SOP#1280 and Section 13 "Corrective Actions". The procedure for investigating and taking appropriate corrective actions for non-conforming work are also described in Section 13. Section 13.3 outlines the procedures for Technical Corrective Actions. Formal corrective action procedures must be followed for non-conforming work that could reoccur (beyond expected random QC failures) or where there is doubt about the laboratory's compliance to its own policies and procedures.

The investigation and associated corrective actions for non-conforming work involving alleged violations of the company's Ethics and Data Integrity policies must follow the procedures outlined in Section 17 – "Data Integrity Investigations".

The reporting of non-conforming work involving alleged violations of the company's Ethics and Data Integrity policies must be reported to a member of the Management Team. Procedures described in Section 17 – "Data Integrity Investigations" are followed.

The laboratory evaluates the significance of the non-conforming work, and takes corrective action immediately. The customer is notified if their data has been impacted. The laboratory allows the release of non-conforming data only with approval of the Technical Manager or his/her designate on a case-by-case basis. Non-conforming data is clearly identified in the final report (see Section 27 – "Reporting the Results").

The discovery of a nonconformance for results that have already been reported to the customer must be immediately evaluated for significance of the nonconformance, its acceptability to the customer, and determination of the appropriate corrective action.

See Section 13 "Corrective Action" and SOP1280 for details on managing non-conforming work.

11.3 Stop Work Procedures

Laboratory supervisors, the Quality Department, and the Management team have authorization to halt non-conforming work at any time. Samples are not analyzed until the problem causing the deviation is corrected. If applicable, the system is monitored until 10 consecutive data points are within control chart limits. After corrective actions successfully eliminate the problem, the corrective actions taken, individual(s) involved, samples affected, and date are noted on corrective action forms and in the appropriate logbooks. Only the Technical Manager (or their designee) can authorize the resumption of affected tests. See section 13 for more information on Corrective Actions.

Section 12- IMPROVEMENT

(TNI V1:M2 – Section 4.10)

Improvement in the overall effectiveness of the laboratory management system is a result of the implementation of the various aspects of the laboratory's management system: quality policy and objectives (Section 3 – "Management"); internal auditing practices (Section 15 – "Internal Audits"); the review and analysis of data (Section 26 – "Quality Assurance for Environmental Testing"); the corrective action (Section 13 – "Corrective Action") and preventive action (Section 14 – "Preventive Action") process; and the annual management review of the quality management system (Section 16 – "Management Reviews") where the various aspects of the management/quality system are summarized, and evaluated and plans for improvement are developed.

Section 13 - CORRECTIVE ACTION

(TNI V1:M2 – Section 4.11)

Corrective action is the action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence. Deficiencies cited in external assessments, internal quality audits, data reviews, customer feedback/complaints, control of nonconforming work or managerial reviews are documented and require corrective action. Corrective actions taken are appropriate for the magnitude of the problem and the degree of risk.

The following section dictates the decision process, procedures and initiation process for corrective actions. It identifies the data used to determine if a problem exists and the actions to be taken.

13.1 General Procedure

The laboratory uses the LIMS database to document and track corrective actions. See SOP#1280 for more information on Corrective Actions.

All deficiencies are first investigated to identify root cause and a corrective action plan is then developed and implemented if deemed necessary. The implementation is also monitored for effectiveness. Teklab technicians, analysts, and supervisors are responsible for initiating corrective actions on routine data reviews where a nonconformance is found that could reoccur (beyond expected random QC failures) or where there is doubt about the compliance of the laboratory to its own policies and procedures. Project Management and the QA Department must be informed immediately if the problem will or may affect client sample results.

Department supervisors are responsible for implementing the corrective action and tracking analysis until the system is in control again. Corrective actions may be entered into the LIMS by any Teklab Personnel. The final corrective action is reviewed by the Quality Department for completeness. The Technical Manager and Quality Officer must approve and close out the completed corrective action in LIMS.

13.1.1 Cause Analysis

When failures due to systematic errors have been identified, the first step is an investigation to determination of the root cause(s) of the problem. When there are non-systematic errors, where the initial cause is readily identifiable or an expected random failures (e.g. failed quality control), a formal root cause investigation is not required.

13.1.2 Selection and Implementation of Corrective Actions

After the root cause(s) has been defined (where applicable), a corrective action plan is then selected and implemented (see Section 13.3 “Technical Corrective Actions” and SOP1280 “Corrective Actions and Root Cause Analysis”).

Where uncertainty arises regarding the best approach for analysis of issues that require corrective action, applicable personnel will recommend corrective actions that are appropriate to the magnitude and risk of the problem and that will most likely eliminate the problem and prevent recurrence

Teklab Management and the Quality Department shall ensure that corrective actions are discharged within the agreed upon time frame. Corrective Action records are maintained in the LIMS database. The records contain details of both the root cause(s) investigation and the corrective action plan. PDF copies of all signed corrective action reports are stored on the Teklab server.

13.1.3 Monitoring of Corrective Action

The Quality Department and Department supervisors (where applicable) will monitor implementation and documentation of the corrective action to assure that the corrective actions were effective. Internal audits may also be used to verify the effectiveness of corrective actions. See SOP 1280 for more information on monitoring corrective actions.

13.2 Additional Audits

Where the identification of non-conformances or departures from normal lab procedures cast doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with the TNI Standard, the laboratory ensures that the appropriate areas of activity are audited in accordance with Section 15 – "Internal Audits" as soon as possible.

13.3 Technical Corrective Action

Sample data associated with a failed quality control are evaluated for the need to be reanalyzed or qualified. Unacceptable quality control results are documented, and if the evaluation requires root cause analysis, the cause and solution are recorded (see Section 11 "Control of Nonconforming Environmental Testing Work"*).*
Analysts routinely implement corrective actions for data with unacceptable QC measures. First level correction may include re-analysis without further assessment. If the test method SOP addresses the specific actions to take, they are followed. Otherwise, corrective actions start with assessment of the cause of the problem.

Corrective action procedures for non-systematic errors or expected random failures are detailed in SOP#1280. All corrective actions are stored in the LIMS and on completion are stored in PDF format on the Teklab server. Corrective actions for non-conformances that may reoccur (beyond expected random QC failures) or where there is concern that the laboratory is not in compliance with its own policies and procedures require that a Corrective Action to be completed (see Section 13.1).

Whenever possible, samples are only reported if all quality control measures are acceptable. If a sample associated with unacceptable quality control measures must be reported, the deviation is clearly documented in the case or sample narrative of the final report. Whenever possible, corrective actions are undertaken to bring the system back in control.

Supervisors, the Quality Department and/or Management may review Corrective Action responses and suggest improvements, alternative approaches, and procedures where needed.

13.4 Data Evaluation

Teklab tracks the precision and accuracy of each analysis through the use of control charts. These control charts are based on the Relative Percent Difference (RPD), Laboratory Control Sample recoveries (LCS) and Matrix Spike recoveries (MSR). The RPD, LCS and MSR are calculated for each run of analysis. Independently verified Quality Control Samples (QC

samples) also are used to determine if the analysis is in control. If the data exceeds the control chart or manufacturer specified limits, the analysis is checked for calibration, standard quality and analytical technique, and the analysis is stopped and corrective action taken.

Section 14 - PREVENTIVE ACTION

(TNI V1:M2 – Section 4.12)

The preventive action plan establishes the process to investigate and track potential non-conformances in Teklab Inc's Quality Management System. The foundation of preventive action is written and accessible documentation of actions taken and subsequent monitoring to determine that preventive actions have been implemented and documented.

Preventive Action Plan
Preventive action plans are part of a proactive process for improvement rather than a reaction to problems or complaints. Preventive action includes the utilization of measurable quality objectives and requirements such as validation and review processes, audits (internal and external), management review, feedback and complaints, and quality system requirements to detect, analyze and remove potential causes of non-conformance. All personnel have the authority to offer suggestions for improvements and to recommend preventive actions, however management is responsible for the actual implementation of preventive action.

The preventive action proactive process consists of:

- reviewing potential problems; deciding the potential cause of the problems;
- deciding the course of action to eliminate the problem from occurring;
- implementing the plan; and then ensuring or verifying the action solved the problem and/or is effective over time.
- Once identified, Preventive action plans are initiated by starting a corrective action in the LIMS.

Monitoring the effectiveness of the preventive action includes, but not limited to, the following:

- control charts;
- performance studies;
- training;
- customer input;
- employee suggestions and input;
- audits;
- management reviews;
- staff meetings
- Scheduled instrument maintenance

Needed improvements and/or potential sources of non-conformance (either technical or Quality related) are identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformances and to take advantage of the opportunities for improvement. A corrective action in the LIMS shall be initiated once a potential nonconformity is identified. Preventive actions shall be monitored by

the supervisor of the relevant department (or their designee); the Quality Department and management. Weekly Management meetings, as part of the management review program, will also monitor the status of preventive action plans. The Quality Assurance Officer is responsible for follow-up and ensuring the action plans are completed.

Teklab's laboratory management reviews the Quality Assurance Plan to ensure its continuing suitability, effectiveness, and compliance with TNI Standards at least annually. This review is documented and includes at least the following:

- Quarterly reports from the quality department concerning the quality system and its testing and calibration activities
- Resources and training
- Reports from any management and supervisory personnel
- Outcomes of any recent internal audits
- Assessments by external bodies
- Results of interlaboratory comparisons or proficiency tests
- Changes in the volume or type of work undertaken
- Feedback from clients
- Complaints
- Corrective and preventative actions

The outcome of this review is to introduce any necessary changes or improvements in the quality system and laboratory operations. A record of this review, its findings and the resulting actions/changes is maintained in the management review file and is archived in accordance with this manual.

A preventative maintenance program is maintained for each instrument. Any equipment found to be out of calibration or indicating problems is taken out of service until the problems are corrected. Records are maintained which document preventive maintenance and repairs to instrumentation and general laboratory equipment. Equipment failures or problems are noted as follows: the nature of the problem, corrective actions taken, the person performing corrective actions and the date. See Section 22 and SOP 1210 for additional information on equipment maintenance.

<u>LIMS Preventive Action</u>
Teklab has a preventive system to plan and test deployments of LIMS modifications to avoid or minimize the potential disruption associated with a LIMS failure.

- Production database: the live LIMS database used throughout the laboratory
- Development database: allows the application programmer to evaluate modifications to the LIMS without affecting live data. These changes are then re-evaluated through test databases.
- Test database: Test databases do not use real time data. They are distributed, by the applications programmer, to designated members of staff. These databases allow modifications to be assessed for potential conflicts and/or errors before updates are finally integrated into the production LIMS.

Section 15 - AUDITS

(TNI V1:M2 – Section 4.14)

15.1 Internal Audits

Audits measure laboratory performance and verify compliance with the TNI Standard, certification requirements, and management system requirements; including analytical methods, SOPs, the Quality Manual, ethics policies, data integrity, and other laboratory policies.

Audits provide management with an on-going assessment of the management system. They are also instrumental in identifying areas where improvement in the management system will increase the reliability of data. Results of the audits (and any associated corrective actions) are reported to the Teklab Board of Directors at least annually.

On a weekly basis,, Teklab, Inc. management, reviews the day to day implementation of policies and procedures that affect the Quality System (see section 16 Management Review and Section 14 Preventive Action).

It is the responsibility of the Quality Officer to plan and organize audits as required by the schedule and requested by management. These audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

These annual audits examine the above stated items as well as the following:

- Personnel training
- SOPs
- Log-In and chain of custody procedures
- Housekeeping
- Balance and micropipette calibrations
- Refrigerator, oven and incubator temperatures
- Fume hood operation and face velocity determinations
- Reagent, solvent and standard documentation
- Instrument maintenance logs
- Corrective action procedures and reports
- Data collection, reduction, validation and reporting
- Waste disposal

The Quality Officer, or their representative, is also responsible for incorporation and/or documentation of changes, including but not limited to, changes in the approved test methods, changes in laboratory equipment, or changes in laboratory personnel. The area audited, the audit findings, and corrective actions are recorded. Audits are reviewed after completion to assure that corrective actions were implemented and effective.

In addition to scheduled internal audits, it may sometimes be necessary to conduct special audits as a follow-up to corrective actions, PT results, complaints, regulatory audits or

alleged data integrity issues. These audits or investigations address specific issues. Review of their effectiveness may occur during the next scheduled audit unless findings are observed that cast doubt on the validity of data; in which case the review must take place as soon as possible.

15.2 External Audits

Management shall ensure that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit.

All records must be made available to Teklab's Accreditation Bodies.

15.2.1 Confidential Business Information (CBI) Considerations

During on-site audits, on-site auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information.

15.3 Performance Audits

Performance audits may be Proficiency Test Samples, internal single-blind samples, double-blind samples through a provider or client, or anything that tests the performance of the analyst and method.

Proficiency Test Samples are discussed in Section 26 – "Quality Assurance for Environmental Testing".

15.4 System Audits

The Laboratory's management system is audited though scheduled management reviews. Refer to Section 16 "Management Review" for more information.

15.5 Handling Audit Findings

Internal or external audit findings are responded to within an agreed time frame. The response may include action plans that could not be completed within the response time frame. A completion date is established by management for each action item and included in the response.

The development and implementation of corrective actions for findings is the joint responsibility of the Quality Department and the relevant Department supervisor (where applicable). Corrective actions are documented through the corrective action process described in Section 13 – "Corrective Actions".

Where the results of the internal audit indicate that operations or procedures are not in compliance, corrective actions must be taken. These corrective actions may include termination of all applicable analysis until the source of the problem can be identified and corrected. Laboratory supervisors, the Quality Department, and the Management team have authorization to halt non-conforming work at any time. All affected samples must be identified and clients whose samples were affected must be notified, in writing, within one week of the problem identification. The analysis cannot be resumed until the problem is demonstrated to be corrected (by the analysis of samples of known concentration), the reason for the problem and all corrective actions are documented and the Technical Manager (or their designee) approves the resumption of analysis. All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. See Section 17 (Data Integrity Investigation) for additional procedures for handling inappropriate activity.

Section 16 - MANAGEMENT REVIEWS

(TNI V1:M2 – Section 4.15)

16.1 Management Review Topics

The following are reviewed (where applicable) to ensure their suitability and effectiveness:

16.2 Procedure

Laboratory management shall continuously review the Quality Assurance Plan to ensure its ongoing suitability, effectiveness, and compliance with NELAP/TNI Standards. The review process includes (but is not limited to) the following:

- Customer service meetings
- Weekly management meeting – attended by management, supervisors, department representatives including the QA department. Minutes of these meetings are recorded by a member of the management team.
- Board of Director meetings

Staff meetings are part of the overall quality system and provide comprehensive departmental interaction that can aid in the planning and co-ordination of activities that may have a laboratory wide impact. Suggested improvements to the quality system, as well as potential sources of non-conformance are discussed as part of the laboratory Preventive Action Plan. The results of these meetings are documented and are incorporated into the laboratory planning system and include the goals, objectives and action plans for the coming year.

Management shall also receive monthly reports from the Quality Department regarding the status of Quality issues including (but not limited to) safety checks, current corrective actions and required laboratory SOP reading. When an ongoing problem is identified in the Quality System that requires attention; it is forwarded to management who assists the Quality Department in monitoring the problem and ensures the issue is resolved in a timely manner where possible.

Section 17 - DATA INTEGRITY

(TNI V1:M2 – Section 4.16)

In addition to covering data integrity investigations, this Section covers all topics related to ethics and data integrity policies, procedures and training.

Teklab Inc is committed to ensuring the integrity of its data and providing valid data of known and documented quality to its clients. The elements in Teklab's Ethics and Data Integrity program include:

- Documented data integrity procedures signed and dated by top management.
- An Ethics and Data Integrity Statement (included in job description) signed by all management and staff upon hiring.
- An Ethics and Data Integrity Statement signed after annual data integrity training. Teklab's Ethics and Data Integrity Policy can be found in the Quality Documents folder on the Teklab Server.
- Appendix A of this Quality Manual.
- Procedures for confidential reporting of alleged data integrity issues.
- An audit program that monitors data integrity (see Section 15 – "Audits") and procedures for handling data integrity investigations and client notifications.

17.1 Ethics and Data Integrity Procedures

The Ethics and Data Integrity Policy provides an over view of the program. Written procedures that are considered part of the Ethics and Data Integrity program include:

- Teklab's Ethics and Data Integrity Policy: "Ethics, Legal Responsibility, & Conflict of Interest" (Appendix A)
- Corrective action procedures (SOP#1280 and Section 13 of this QAM)
- Procedure for Data Integrity Investigations (See Section 17.4 Investigations)
- Data Integrity training procedures (See Section 17.2 Training)
- Internal audit procedures (SOP#1270 and See Section 15 of this QAM)

17.2 Training

Data integrity training is provided as a formal part of new employee orientation and a refresher is given annually for all employees. Training courses in data integrity, ethical and

legal responsibilities, include the potential punishments and penalties for improper, unethical or illegal actions. Attendance for required training is mandatory and is monitored through a signature attendance sheet.

Evidence must be on file that each employee has read, acknowledged and understood their personal, ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

Data integrity training emphasizes the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. Topics covered are provided in writing and provided to all trainees.

17.3 Confidential Reporting of Ethics and Data Integrity Issues

Confidential reporting of data integrity issues is assured through the following procedures:

- Teklab Inc's Ethics and Data Integrity Policy ("Ethics, Legal Responsibility, & Conflict of Interest" see Appendix A)
- Procedures for reporting Data integrity and Ethics issues outlined in initial and ongoing annual training. Training slides are available in the Quality Documents folder on the Teklab server.

17.4 Investigations

All investigations resulting from data integrity issues are conducted confidentially. They are documented and notifications are made to clients who received any negatively affected data that did not meet the client's data quality requirements. Procedures for investigation are detailed below:

- Any Teklab personnel who learn of a non-compliance related incident through the reporting protocol should immediately inform a member of Teklab Management verbally or in writing.
- Any ethical matters discussed with management personnel will remain confidential within Teklab's management. In cases involving possible violations of the law or TNI regulations, Teklab may be required to reveal information to the proper authorities.
- Teklab management is responsible for determining the seriousness of the incident.
- Teklab's management team shall thoroughly investigate each incident and retain all evidence and records.
- Investigation Documentation Includes:
    - Date of investigative Report
    - Date Incident First Reported
    - Date of Incident Occurrence
    - Type of Issue / Incident
    - Full Description of Issue

- Description of Investigation
- Description of Resolution

Section 18 – PERSONNEL AND TRAINING

(TNI V1:M2 – Section 5.2)

Teklab Inc employs competent personnel based on education, training, experience and demonstrated skills as required. The laboratory's organization chart can be found in Appendix B.

18.1 Overview

All personnel are responsible for complying with all quality and data integrity policies and procedures that are relevant to their area of responsibility.

All personnel who are involved in activities related to sample analysis, evaluation of results or who sign test reports, must demonstrate competency in their area of responsibility. Appropriate supervision is given to any personnel in training and the trainer is accountable for the quality of the trainees work. Personnel are qualified to perform the tasks they are responsible for based on education, training, experience and demonstrated skills as required for their area of responsibility.

The laboratory provides goals with respect to education, training and skills of laboratory staff. These goals are outlined in the 1031 SOP and the employee's job description. Training needs are identified at the time of employment and when personnel are moved to a new position or new responsibilities are added. Ongoing training, as needed, is also provided to personnel in their current jobs. The effectiveness of the training must be evaluated before the training is considered complete.

A log of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory records is maintained and stored in hard copy by the Quality Department.

18.2 Job Descriptions

Job descriptions are available for all positions that manage, perform, or verify work affecting data quality, and are located in each employee's electronic training file located on the Teklab Inc Server. These files are stored securely. An overview of top management's responsibilities is included in Section 3 – "Management".

18.3 Training

All personnel must perform a successful Initial Demonstration of Capability prior to initiation of assigned analysis (See SOP#1031 for IDOC and Certification Statement Requirements).

All new personnel are trained on their applicable analysis by an experienced Teklab employee. Additional training needs for each individual are determined through review of their resume and work experience and one on one interaction with the individual's supervisor and/or trainer. All personnel must successfully complete an IDOC prior to termination of training. Ongoing training is determined on a case by case basis by the individual's supervisor or a representative of the Quality Department. See SOP#1031 and Section 19 of this QA Manual for more information on IDOCs/ADOCs.

The Quality Department is responsible for tracking all initial introductory training. Department Supervisors are responsible for initiating, coordinating and monitoring on the job training for analysts within their department. Training records maintained by the Quality Department are stored securely on the Teklab Inc Server and include personnel qualifications, education, experience and training pursuant to the requirements set forth in sections 4, 5 and 19 of this Quality manual. Training files are considered up-to-date when the following items are present:

- Certification that the employee has completed initial safety and quality training.
- Documentation of Initial Demonstration of Capability (IDOC).
- Certification that the employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to their job responsibilities.
- Certification that the technician has read, understood and agreed to perform the most recent version of the approved standard operating procedure.
- Documentation of academic education and of training courses or workshops on specific equipment, analytical techniques, or laboratory procedures.
- Job description signed by the employee that includes an agreement that they are aware of their ethical and legal responsibilities and will avoid any conflict of interest.
- Documentation of Annual Demonstration of Capability (ADOC) on applicable methods.

18.3.1 Ethical/Legal Responsibilities and Conflict of Interest

Teklab is organized so that confidence in its independence of judgment and integrity are maintained at all times and has processes to ensure that its personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work. Teklab has a proactive program for prevention and detection of improper, unethical or illegal actions. See Appendix A for Teklab's Ethics and Data Integrity Policy and Section 17 for more on Data Integrity.

All new personnel are trained during orientation and all personnel are trained, at least annually, on data integrity, ethical behavior, legal responsibilities and conflict of interest. Each Teklab job description includes an agreement with the employee that they are aware of their ethical responsibilities and will avoid any conflict of interest. See also Teklab Inc. NELAP Policy Ethics, Legal Responsibility, & Conflict of Interest for policy discussed during training.

Teklab Inc's legally responsible parties are the signatories in Section 1 (Introduction and Scope) of the Quality Manual.

18.3.2 Training for New Staff

All new staff members are given introductory training and orientation upon arrival. The training is documented on a training attendance sheet that outlines what was covered during the training sessions.

Training topics include (but not limited to):

- Data Integrity training
- Safety training
- Quality training

Initial Laboratory Training:

- All documentation involved with a new and unfamiliar task is read and understood by the trainee. Reading forms are initial and dated by the employee confirming that they have read and understood the material.
- Training is under the direct supervision of a qualified analyst.
- During the time the analyst is in training, the trainee may sign laboratory notebooks, logbooks, worksheets, etc. But they must be co-signed by the trainer who is responsible for the data generated.
- The trainee demonstrates competency in the new task before they can operate independently. The competency for a test method is accomplished by a successful IDOC as defined in Section 19 of this Quality Manual.
- Training documentation is maintained in the employees training record, which is stored electronically on the Teklab Inc server.

18.3.3 Ongoing Training

The employee attests, through signature, that they have read, understood, and agree to perform the latest version of any SOPs or policies that the analyst is responsible for following:

- Annual refresher Data Integrity Training.
- Annually, the analyst shows continued proficiency in each method they perform (see Section 19 on IDOC s and ADOCs)
- Attending training related to job function as applicable.
- Maintaining training documentation in the employees training record.
- Monthly Safety training.
- Monthly Quality training.

18.3.4 Education/Experience

Job descriptions for all Teklab personnel are maintained by the quality department. Each employee must read and sign their job description upon hiring or changing positions within the laboratory. The signed job descriptions are placed in each employees training file.

18.3.4.1
The laboratory ownership shall designate at least one individual as LABORATORY DIRECTOR. The laboratory director shall have overall responsibility for the operation of the laboratory. The laboratory director shall also:

1. Hold a minimum of a bachelor's degree in chemistry or a related science or have completed enough course work in chemistry to equal a minor in chemistry or have at least 10 years non- academic analytical experience
2. The laboratory director shall be an employee of the laboratory and on-site at least 50% of the time.

18.3.4.2
The laboratory ownership shall designate at least one individual as the Technical Manager (or however named). These persons shall also:

1. Hold a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry
2. Have at least two (2) years of experience in the environmental analysis of representative inorganic or organic analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.
3. Have a general knowledge of the analytical methods for which data review is performed.

See the TNI Standard V1M2 Section 5.2.6.2 for a list of Technical Manager qualification exceptions.

18.3.4.3
The laboratory ownership shall designate at least one individual as the Quality Officer. These persons shall also:

1) Hold a bachelor's degree in chemistry or related sciences or have completed enough course work to equal a major in science; and/or
2) Have a minimum of one year experience as an analyst in a laboratory and/or
3) Have documented training in quality assurance and quality control (QA/QC) and at least 3yrs of experience in a Quality Assurance setting
4) Where applicable, have functions independent from laboratory operations;
5) Have a general knowledge of the analytical methods for which data review is performed;
6) Be an employee of the laboratory, but free from outside or managerial influence, so that they may objectively perform assessments and evaluate data

18.3.4.4
The laboratory director and/or ownership shall designate at least one individual as LABORATORY SUPERVISOR. The laboratory supervisor(s) shall:

1) Hold a minimum of a bachelor's degree in chemistry or related sciences or have completed enough course work in chemistry to equal a major in chemistry, or;
2) Have had a minimum of five years experience in the analyses pertaining to the applicable fields of testing,;

The laboratory ownership may designate a laboratory supervisor as laboratory director. The Laboratory director/supervisor must fulfill the requirements of sections 18.3.4.1 and 18.3.4.4 above.

18.3.4.5
The laboratory director or supervisors shall designate the ANALYSTS. Analysts shall:

1) Hold a bachelor's degree in chemistry or related sciences or have completed enough course work in chemistry to equal a major in chemistry; or
2) Have had a minimum of two years experience in the analysis pertaining to the applicable fields of testing for which the laboratory is accredited; or
3) For those instruments listed in 18.3.4.6 below:
   A) either:
      i) have satisfactorily completed a minimum of four hours training that is offered by the equipment manufacturer, a professional organization, a university or another qualified training facility; or
      ii) served a two-week period of apprenticeship under an experienced analyst; and
   B) After appropriate training pursuant to subsection 18.3.4.5(3A), perform the Initial Demonstration of Capability (IDOC) study as specified in Section 19 of this Quality Manual and the TNI 2009 Standard (See SOP1031 for IDOC procedure); and
   C) Have on file annual documentation indicating one of the following:
      - Acceptable performance on a blind sample,
      - Another Initial demonstration of capability (IDOC),
      - four consecutive in-control laboratory control samples,
      - a documented process of analyst review using quality control (QC) samples
      - a certification that the technician has read, understood and agreed to perform the most recent version of the method, the approved method or standard operating procedure.

      Such documentation shall demonstrate that the required training is up-to-date.
4) Be an employee of the laboratory, contract employee, or contracted temporary agency staff; and

The Technical Manager or supervisors may designate individuals as ANALYSTS-IN-TRAINING. Analysts-in-training must at least meet the requirements in subsection 18.3.4.5.1 or 18.3.4.5.2 and be in the process of meeting the requirements of subsection 18.3.4.5 (3a). A laboratory

supervisor, analyst or data auditor shall review and verify all data produced by analysts-in-training.

18.3.4.6
Analyses performed utilizing Automated Colorimetric (AC), Gas Chromatograph (GC), Gas Chromatograph/Mass Spectrometer (GC-MS), Inductively Coupled Plasma (ICP), Inductively Coupled Plasma Mass Spectrometer (ICP-MS), are only acceptable for the purposes of this manual when performed by a laboratory employee who meets the requirements in subsection 18.3.4.5 above.

18.3.4.7
A TECHNICIAN is a person who holds a minimum of a high school diploma or its equivalent. Any exceptions to this must be noted in the technicians job description. A technician must:

1) either:
    A) Have satisfactorily completed a minimum of four hours training that is offered by the equipment manufacturer, a professional organization, a university or qualified training facility; or
    B) Served a two-week period of apprenticeship under an experienced analyst or technician;
2) After appropriate training pursuant to subsection 18.3.4.7(1), perform the Initial Demonstration of Capability (IDOC) study as specified in Section 19 of this Quality Manual and the TNI 2009 Standard (See SOP1031 for IDOC procedure); and;
3) Have on file annual documentation indicating one of the following:
    - Acceptable performance on a blind sample,
    - another Initial Demonstration of Capability (IDOC),
    - four consecutive in-control laboratory control samples,
    - a documented process of analyst review using quality control (QC) samples
    - a certification that the technician has read, understood and agreed to perform the most recent version of the method, the approved method or standard operating procedure.

    Such documentation shall demonstrate that the required training is up-to-date.

18.3.4.8

A person may be allowed to serve in any capacity as defined in subsections 18.3.4.1 through 18.3.4.7 when the person does not meet the training, educational, or experience requirements for the position under one of the following conditions:

A) Experience as an offset for educational requirements (one year of experience performing the applicable duties equals one year of education);
B) Education as an offset for experience requirements (one year of applicable education beyond a bachelor's degree equals one year of experience);
C) For analysts and technicians, have six months laboratory experience as offset for the training and apprenticeship requirements set forth in 18.3.4.5 or 18.3.4.7 as applicable. Laboratory experience must be in the analytical technique for which the offset is requested.
D) For analysts and technicians, demonstration of ability to properly perform representative test procedures.

Section 19 - IDOC & ADOC

(TNI V1:M4 – Section 1.6)

19.1 Initial Demonstration of Capability (IDOC)

The IDOC is a procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.

Before reporting any data with a given method, a satisfactory IDOC is performed. Thereafter, each analyst demonstrates continuing proficiency through the procedures outlined in Annual Demonstration of Capability below.

Each analyst performs an IDOC prior to initiation of assigned sample analysis, unless the IDOC is not applicable to the approved test method, such as total volatile solids, pH, color, odor, temperature, dissolved oxygen or turbidity. Thereafter, continuing demonstration of method performance is accomplished per the QCI for the method. IDOC studies are repeated whenever there is a change in analyst, instrument type, or approved test method that requires a change to the procedure in the SOP.

Teklab documents the completion of each demonstration of capability on a certification statement form. IDOCs are stored in the Teklab LIMS, and documented in the Employee Training Database (on the Teklab server), and in the employee's electronic training files which are stored on the Teklab Inc Server. All records related to the demonstration are retained.

IDOCs (Demonstration of Capability) are performed:

- Before using any method
- Each time there is a change in instrument type, personnel or *method and
- If the laboratory or analysts has not performed the method in a twelve-month period.
- When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited method, an IDOC shall be performed for that analyte

*Changes in method are assessed by the Technical Manager (or their designee) and the applicable laboratory Supervisor. Changed deemed as significant require an IDOC to be performed.

The IDOC(s) for each analyst is stored in the Teklab LIMS, and documented in the Employee Training Database, in the employee's electronic training file and on employee electronic Demonstration of Capability (DOC) Forms which are all stored on the Teklab Inc Server. The DOC identifies the analyst(s) involved in preparation and/or analysis; matrix; analyte(s), class of analyte(s), or measured parameter(s); the method(s) performed; the laboratory-specific SOP used for analysis; and the date(s) of analysis. The LIMS and server copy of the IDOC also contain a summary of the results used to calculate the mean recovery and standard deviations.

All raw data, preparation records, and calculations for each IDOC are retained and are available for review.

IDOC procedures are outlined in SOP#1031 - IDOCs and ADOCs

Interim Data Generation
Data produced by analysts and instrument operators while in the process of obtaining the required training or experience is acceptable when reviewed and validated by a fully qualified analyst or the immediate supervisor.

19.2 Annual Demonstration of Capability (ADOC)

After the initial demonstration of capability is completed, on-going proficiency is maintained and demonstrated at least annually. Each analyst is expected to consistently meet the QC requirements of the method, the laboratory SOP, client requirements and/or the TNI Standard. ADOCs are documented in the Employee Training Database (by the Quality Department), and in the employee's electronic training files which are stored on the Teklab Inc Server. All records related to the demonstration are retained.

Teklab can use the following procedures to demonstrate ongoing DOC:

a) acceptable performance of a blind sample (single blind to the analyst);
Note: Successful analysis of a blind performance sample on a similar method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5030/8260) would only require documentation for one of the tests.
b) another initial DOC;
c) at least four (4) consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing LCSs for each method for each analyst each year;
d) a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary;
e) if a) through d) are not technically feasible, then analysis of real-world samples with results within a predefined acceptance criteria (as defined by the laboratory or method) shall be performed.

Section 20 - ACCOMODATIONS AND ENVIRONMENTAL CONDITIONS

(TNI V1:M2 – Section 5.3)

20.1 Environmental

Prior to the initiation of new work, the laboratory management reviews the work to ensure that it has the appropriate facilities and resources to accomplish the work. Management

also provides adequate workspaces to ensure an unencumbered work area for performing the approved test methods.

The laboratory is designed, operated and arranged so that incompatible analyses are separated and the potential for sample contamination is minimized. Such environmental conditions include:

- The volatile organic laboratory has a separate ventilation system. Access to the volatile organic laboratory is limited to use only as necessary. Air volatile analysis is isolated at a separate facility located at the Teklab Air Laboratory.

- The microbiology lab has access restricted to only microbiology and quality assurance department personnel. All fecal coliform analyses are performed at a separate time from any other microbiology analysis, with proper disinfection of the area between analysis times.

- The laboratory has one exhaust hood for sample receipt, three for inorganic analysis, one for metals prep, and three for organic prep. Organic analysis also has three fume absorbers.

Environmental conditions are monitored as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Environmental tests are stopped and corrective actions are taken and documented when the environmental conditions jeopardize the results of environmental tests.

New laboratory facilities shall be designed, operated and arranged so that all of the specifications of this section are met.

20.2 Work Areas

Teklab's facilities are maintained to permit the production of analytical data that meets the data quality of objectives of the applicable environmental regulation. Areas that affect the quality of laboratory activities are defined as any area within the physical boundaries of the building, except for the restrooms, lunch room and all hallways.

Good housekeeping is stressed. Employees must keep work spaces, instrumentation, and equipment clean and unencumbered.

The laboratory procedure for good housekeeping includes such measures as
- A part-time janitor
- periodic dedicated clean up days
- employees responsible for cleanliness of their own work area

20.3 Floor Plan

Floor plans can be found in Appendix C of this QA Manual.

20.4 Building Security

Areas that affect the quality of laboratory activities are secure areas and access is limited to Teklab, Inc. employees, anyone else entering these areas must be escorted by a Teklab, Inc. employee. Access to the laboratory facilities, during non-business hours, is controlled through a monitored building alarm system. The parking lot is also under video surveillance.

Section 21 - ENVIRONMENTAL METHODS AND METHOD VALIDATION

(TNI V1:M2 – Section 5.4 and Sections 1.4, 1.5 and 1.6 of Technical Modules TNI V1:M 3-7)

Methods and/or procedures are available for all activities associated with the analysis of the sample including preparation and testing. For purposes of this Section, "method" refers to both the sample preparation and determinative methods.

All methods are in accordance with applicable professional technical standards, U.S. & Illinois EPA requirements. Teklab uses only methods mandated by legal requirements, recognized published methods or methods developed and validated by Teklab. Methods are not used for reporting results until competence for each matrix is demonstrated. Personnel are not permitted to depart from approved procedures without the proper validations and approval of the Technical Manager and/or the Quality Assurance Officer, and approval of the client.

All analytical methods performed at Teklab have internally written Standard Operating Procedures (SOPs) or are copies of published methods, with any changes or selected options documented. Methods are based on the applicable reference method or methods (i.e. SW846, EPA 600, Standard Methods, NIOSH, IDPH, etc.).

Before being put into use, a test method is confirmed by a method validation process.

21.1 Method Selection

The laboratory selects methods that are appropriate to the customer needs. When the regulatory authority mandates or promulgates methods for a specific purpose, only those methods will be used.

If a method proposed by a customer is considered to be inappropriate or out-of-date, the customer is informed and the issue resolved before proceeding with analysis of any samples (see Section 6 – Review of Requests, Tenders and Contracts). If a method is not specified by the customer, an appropriate method will be selected using the process outlined below:

When a method is not specified by the customer, or the proposed method is inappropriate, the laboratory will select a method that is appropriate to the end use of the data. The laboratory selects methods that are appropriate to the customer needs. The customer will be informed of the selected method and must approve its use before being used to report data. When the regulatory authority mandates or promulgates methods for a specific

purpose, only those methods will be used (see Section 6 – Review of Requests, Tenders and Contracts).

If there is not a regulatory requirement for the parameter/method combination, the parameter/method combination need not be validated as a non-reference method if it can be analyzed by another similar reference method of the same matrix and technology. (TNI V1 M4 1.4 - Method Selection)

21.2 Method Validation

Method Validation (MV) studies are used to verify the analytical procedure at different concentrations. An MV study is performed for each new analysis or test method and whenever a modification in methodology occurs that could affect the quantitation range of the analysis. MV studies include the determination of the following:

- Method detection limit – The method detection limit (MDL) is defined as the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results This number is used in LIMS and appears on final reports. The MDL is used to accommodate variances in multiple instrument MDL determinations and to minimize ongoing adjustments to the reporting limits.

- MDL_s - The method detection limit based on spiked samples

- MDL_b - The MDL based on method blanks

- PQL (practical quantitation limit) – The lowest level or concentration of an analyte that can be reported with a specific degree of confidence. For test methods utilizing a calibration curve, the PQL is equivalent to the lowest calibration standard. The PQL must be greater than the MDL and no greater than ten times the MDL. If regulatory limits are provided by the client, the PQL must be equal to or less than these.

- RL (Reporting Limit) – The PQL multiplied by any dilution or preparation factors. The RL appears on the final report. If a CRQL (client requested quantitation limit) exists for the sample and is greater than the final RL, the RL can be replaced with the CRQL at the client's request.

- MV (Method Validation Study) – The initial test method and/or instrument requirements of TNI and/or the referenced test method to validate that the laboratory is capable of achieving the required qualitative and quantitative detection and the required precision and accuracy of the method

See SOP 1030 'Method Detection Limits & Method Validation Studies' for detailed procedures on MDLs.

Selectivity

Selectivity is evaluated by following the checks established within each method. Examples are mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatograph retention time windows, instrument blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, electrode response factors, and correlation coefficients. The acceptance criteria for mass spectral tuning is documented in the appropriate method SOP.

21.3 Estimation of Uncertainty of Measurement

Estimation and uncertainty of measurement are provided to clients upon request.

- If the standardized test method contains guidance to the uncertainty of evaluation, the method guidance is used for determination.
- If the standardized test method gives a typical uncertainty of measurement for test results this figure is quoted, provided there was full compliance with the test method in the performance of the test.
- If a standardized method implicitly includes the uncertainty of measurement in the test results, the results are reported accordingly.

Otherwise the estimation of uncertainty of measurement will be reported as follows:

The confidence interval for the test method determined from the standard deviation of Laboratory Control samples or QC samples utilized by the laboratory in determining batch acceptance for the test method will be provided with the data as a statement of uncertainty of measurement. If the sample measurement is near the reporting limit or detectable limit, additional information will be given on the variability of low level data. A statement of sample homogeneity will also be included, as well as any other sample related factors that may have lead to uncertainty of measurement.

In cases where the test method precludes rigorous, metrologically and statistically valid calculation of uncertainty of measurement, all the components of uncertainty of measurement are identified, a reasonable estimation on uncertainty is made, and the result is reported with explanation on the uncertainty.

21.5 Control Charts

Control charts are used to monitor the accuracy and precision of the procedures used at Teklab. They are used to determine what types of bias, if any, are occurring in analysis and to determine when an analysis or procedure is out of control.

PRECISION CONTROL CHARTS:
The precision control chart checks the duplicity of our methodologies. It uses the relative percent difference (RPD) between duplicate analyses.

ACCURACY CONTROL CHARTS:
The accuracy control chart checks the percent recovery of our methodologies. These check the percent recovery from LCSs and MSRs (Matrix Spike recoveries). This control chart cannot be made until at least twenty observations are made using samples of a known concentration. The Shewhart X-bar type chart is used for this measurement. The center line is the mean %R, the UWL and LWL (Upper and Lower Warning Limits) are calculated and plotted at +/- 2*sd; this represents a limit within which 95% of all subsequent %R calculations should fall, to ensure that the analysis/methodology is under control. The UCL and LCL (Upper and Lower Control Limits) are +/- 3*sd; this represents a limit within which 99% of all subsequent %R calculations should fall to ensure that the analysis/methodology is under control.

FREQUENCY AND CONSTRUCTION OF CONTROL CHARTS:
Data for accuracy and precision control charts will be updated continuously via the LIMS. The need to monitor a control chart for a particular analysis will be evident to the department supervisor if the quality control indicators for the test are not falling around the mean of the upper and lower control limits for the test. Data used to create control chart limits must be thoroughly reviewed for obvious outliers before inclusion in the control chart data set. Laboratory control limits for accuracy and precision will be updated as needed, with approval from the Technical Manager.

INTERPRETATION OF CONTROL CHARTS:
The control charts are used to trend results and look for problems or bias in the way an analysis is run. If a condition exists which indicates an out of control process or process bias, as defined by typical analysis of Shewhart control charts (example: Seven points on same side of an X-bar chart or a point above or below the UCL or LCL), a significant event will have occurred. In that event the Quality Assurance Officer, Technical Manager and any needed technicians or analysts will conduct an investigation to determine the cause or causes of the event and corrective action shall be implemented. After determination of a significant event, the applicable control charts will be updated with every new data point until the analysis is once again in control. A minimum of 10 data points will be plotted before the analysis can be said to be in control, once again.

21.6 Control of Data

To ensure that data are protected from inadvertent changes or unintentional destruction, the laboratory uses procedures to check calculations and data transfers (both manual and automated). See Section 5 – Control of Records for more information.
Note: Employees should not save important documents to the C Drive of their PCs, as information may be lost if the computer's hard drive fails. Documents should either be saved to designated folders on the F Drive or user-defined U Drives; both of which are located on the Teklab Server.

21.6.1 Computer and Electronic Data Requirements

The laboratory assures that computers, user-developed computer software, and automated equipment used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data are:

- documented in sufficient detail and validated as being adequate for use;
- protected for integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and
- held secure including the prevention of unauthorized access to, and the unauthorized amendment of, computer records. Data archive security is addressed in Section 5 "Control of Records" and building security is addressed in Section 20 "Accommodations and Environmental Conditions".

Computers and instrumentation are tracked via a database that contains information such as the PC/instrument name, operating system and associated software. Purchased Microsoft Office open licenses are also tracked in the database. The database is stored securely in the IT folder on the Teklab Server.

21.6.2 Data Reduction

The analyst calculates final results from raw data or appropriate computer programs provide the results in a reportable format. The test methods or SOPs provide required concentration units, calculation formulas and any other information required to obtain final analytical results.

The laboratory has manual integration procedures that must be followed when integrating peaks during data reduction. See SOP4026 Manual Integrations.

Data is collected and reported by analysts after completion of a run of analysis in which all Quality control parameters are within the specified limits.

Calculations used to determine concentrations of the analytes for each parameter are included or referenced in each SOP. The calculations involve calibration factors that relate a known concentration to a measured concentration. The units are based on the calibration concentrations that are also defined in each SOP. Raw data and final results are recorded in the analysis logsheet (by the analyst), or the original printed data package from the instrument is retained. The raw results and corresponding quality control results are downloaded or manually entered into the Laboratory Information System (LIMS). The lab supervisor or other data validator reviews the calculated results, ensures that the data is free from transcription and calculation errors and checks the corresponding quality control information (ICB, ICV, CCBs, CCVs, MS/MSDs and RSD/RPD results). If the quality control

information is within specified limits and the calculations are correct, the lab supervisor or other data validator validates the records in the LIMS. See the applicable SOP (1020, 1270, 1280 and 1290) for identification of individuals responsible for assessing each QC data type.

Data for pH, temperature, Dissolved Oxygen, Turbidity, ORP and conductivity is read directly from the instrument. All other data must be calculated manually to some degree. It is the responsibility of the analyst to convert raw data into reportable values and the lab supervisor or other data validator to ensure calculations are correct and that quality control checks are within specified limits.

All analysis have their own individual data packet to record analysis, unless computer generated reports are deemed acceptable by the Quality Assurance Officer and/or Technical Manager. See SOP 1291 Record Retention and Access. Data packets and/or computer-generated reports are maintained by the analysts responsible for performing the analysis and kept in the appropriate area of the laboratory. The data packet contains a cover sheet and a data sheet or sheets to record reagent and standard solution lot numbers. The data packets also contain information on any cleanup or separation procedure, sample ID codes, volumes and weights, if applicable. Problems noted during analysis are documented on the cover sheet of the data packet or computer generated report.

All raw data must be either retained in hard copy format and/or scanned to PDF and is maintained as described in Section 5 "Control of Records".

21.6.3 Data Review Procedures

Data review procedures are located in Section 26.4 – "Data Review".

Section 22 - CALIBRATION REQUIREMENTS: Equipment and Instruments

(TNI V1:M2 – Sect 5.5 and Section 1.7 of Technical Modules TNI V1:M4)

22.1 General Equipment Requirements

Any equipment procured in the support of tests must be of adequate quality to sustain confidence in the laboratory's tests, as specified by the SOP for each analytical method. Laboratory supervisors are responsible for informing the quality department of new equipment procurements and creating a maintenance log on the LIMS system. Where no independent assurance of the quality of the equipment is available, the equipment must be shown to produce acceptable results for the test method, within quality control limits of the test, before onset of sample analysis.

See General Equipment Maintenance SOP1210 for details on performance and documentation of equipment maintenance, inspection and cleaning. Manuals provided by the manufacturer of the equipment provide information on use, maintenance, handling and storage of the equipment. Any item of equipment subjected to overloading or mishandling which gives questionable results, or has been shown by verification or otherwise to be defective, shall be taken out of service. That equipment shall be clearly identified with a sign stating "OUT OF SERVICE" and wherever possible, stored in the rear storage area until

it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests. If it is shown that previous tests are affected, then procedures for nonconforming work are followed and results are documented (see Section 11 – "Control of Nonconforming Environmental Testing Work" and Section 13 – "Corrective Action"). The laboratory shall maintain documentation of all maintenance, calibration and instrument operation activities. Proper instrument maintenance is essential to the success of any analytical laboratory. Teklab's policy is to include instrument troubleshooting and maintenance as standard training for its analysts. Analysts gain a more thorough understanding of the analytical methodology and produce higher quality analytical results when they are capable of solving problems associated with instrument operation. Teklab employs service agreements and/or onsite/offsite service support to supplement our maintenance program whenever the analytical instrumentation requires expertise beyond our capabilities or safety concerns dictate the use of individuals with specialized training.

All instruments must be clearly labeled with unique identification (e.g. Milestone MPR-600/6S, Microwave 1).

Equipment is operated only by authorized and trained personnel (see Section 18 – "Personnel"*)*.

Test equipment, including hardware and software, are safeguarded from adjustments that would invalidate the test result measurements by limiting access to the equipment and using password protection where possible (see Sections 21.6 – "Control of Data" and 5.2 "Records Management and Storage").

Each item of equipment and software used for testing and significant to the results is uniquely identified. Records of equipment and software are maintained and include the following:

a) identity of the equipment and its software;

b) manufacturer's name, type identification, serial number or other unique identifier;

c) checks that equipment complies with specifications of applicable tests;

d) current location;

e) manufacturer's instructions, if available, or a reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

g) maintenance carried out to date; documentation on all routine and non-routine maintenance activities and reference material verifications;

h) any damage, malfunction, modification or repair to the equipment;

See Section Appendix F for a current list of Teklab equipment.

The laboratory documents and maintains records, whether hard copy or electronic, of instrument and equipment calibrations, including at a minimum:

- Calibration procedures, calibration frequency, calibration acceptance criteria;
- Procedures to label all calibration curves, including the date, approved test method, analyte, standard concentrations, and instrument response; and
- Procedures to label the axes of the calibration curve.

For electronic data processing systems, which automatically compute the calibration curve, the system records the equation for the curve and correlation coefficient. Laboratory personnel record correlation coefficient when the calibration curve is prepared manually.

See Section 5 of this manual for more information on Control of Records.

22.2 Support Equipment

The laboratory has equipment that is applicable to its accreditation**.**

Support Equipment includes, but is not limited to: balances, ovens, refrigerators, freezers, incubators, temperature measuring devices, and volumetric dispensing devices.

Before being placed into service, support equipment shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. All support equipment is maintained in proper working order. Records are kept for all repair and maintenance activities, including service calls. Balances are calibrated annually by a member of the Quality Department. Records of calibrations are stored in the Quality Folder on the Teklab server.

All raw data records, where applicable, are retained to document equipment performance. These records include logbooks, data sheets, or equipment computer.

See SOP1210 for more information.

22.2.1 Support Equipment Maintenance

Regular maintenance of support equipment, such as balances is conducted at least annually. Maintenance on other support equipment, such as ovens, refrigerators, and thermometers is conducted on an as needed basis.

Records of maintenance to support equipment are documented in Instrument Maintenance Logs located in the LIMS or hard copy maintenance logbooks.

22.2.2 Support Equipment Calibration

Relevant SOPs:
SOP 1180 - Balance use, maintenance and calibration
SOP 1190 - Auto Pipet and Syringe use, maintenance and calibration
SOP 1200 - Dessicant maintenance
SOP 1210 - General Equipment Maintenance
SOP 1220 - Thermometer use, maintenance and calibration.

SOP 1230 - Refrigerator and freezer use, maintenance and calibration.
SOP 1240 - Oven use, maintenance and calibration.

All support equipment is calibrated or verified at least annually over the entire range of use using NIST traceable references where available. The results the calibration of support equipment is within specifications, otherwise:

- equipment is removed from service until repaired
- records are maintained of correction factors to correct all measurements. If correction factors are used this information is clearly marked on or near the equipment.

Support equipment such as balances, ovens, refrigerators, freezers, and water baths are verified with a NIST traceable reference if available, each day prior to use, to ensure operation is within the expected range for the application for which the equipment is to be used. Acceptance criteria can be found in the applicable calibration SOP.

The laboratory identifies each refrigerator, freezer, thermometer, oven, and incubator in a way that establishes their use and distinguishes them from other similar equipment in the laboratory.

Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) are checked for accuracy on a quarterly basis.

The laboratory checks the calibration of infra-red thermometers at least quarterly against a NIST-traceable thermometer. The comparisons are made at the temperature at which the thermometer will be used.

The laboratory shall monitor and control method specific temperature requirements for incubators, heating blocks and water baths each day of use. The laboratory maintains documentation of the results.

The calibration temperatures of laboratory hot blocks used for digestion are checked at least annually and after repairs. When digital readout is in units other than temperature, correlation of the digital readout to the temperature required for the test is documented. Temperature or digital readout is documented each day of use.

Laboratory personnel calibrate turbidimeters on a daily basis or before each use, whichever is less frequent, pursuant to section 5.2.1 of “Manual for the Certification of Laboratories Analyzing Drinking Water”.

See applicable calibration SOPs for more information. See Sections 4 “Document Control” and 5 “Record Control” for details regarding documentation.

A pH meter having the accuracy of at least +/- 0.05 pH units and a scale readability of at least 0.01 pH units must be used for pH analysis.

A conductivity meter with an error not exceeding 1% or one μmhos/cm, whichever is greater, must be used by the laboratory.

All glassware used for purposes that may subject it to damage from heat or chemicals shall be of borosilicate glass. All volumetric glassware used for standard preparation shall be ASTM class A.

Teklab uses Class S or NVLAP approved certified weights to calibrate balances. The laboratory re-certifies its reference weights at least once every five years. Other laboratory weights are calibrated annually by a member of the Quality Department. Records of the calibrations are stored in the Quality Folder on the Teklab Server.

The laboratory ensures that the NIST traceable thermometer is calibrated at least once every five years.

22.3 Analytical Equipment

22.3.1 Maintenance for Analytical Equipment

All equipment is properly maintained, inspected, and cleaned.

Maintenance of analytical instruments and other equipment may include regularly scheduled preventive maintenance or maintenance on an as-needed basis. Instrument malfunction is documented in the LIMS, which become part of the laboratory's permanent records.

22.4 Instrument Calibration

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. Calibration requirements are included in laboratory SOPs. Generally, procedures and criteria regarding instrument calibrations are provided or referenced in the individual SOPs.

Section 22.2.2 includes information on calibration of support equipment. The following Section covers calibration of analytical equipment.

22.4.1 Initial Instrument Calibration

Verification of instrument calibration will include a blank (ICB) and either an Initial Calibration Verification (ICV) or QC sample (independent reference sample) at the beginning and end of each run of analysis and at least once every 20th sample in between (CCB/CCV) unless the analytical method does not require it, such as in methods which utilize internal standards. Any ICV off by more than the limits specified for that analysis or any QC sample outside the concentration range provided with the sample will cause the run to be rejected and require corrective action. All new instruments must have method detection limit (MDL) studies and method validation studies performed before the analysis of any samples. See the applicable

method SOP for more information on calibration, ICB/ICV/CCB/CCV acceptance criteria and equipment maintenance requirements.

The laboratory performs an initial calibration of all instrumentation and equipment as specified in the approved laboratory SOP. The laboratory uses calibration standards traceable to national standards where available. When traceability is not applicable, the laboratory produces evidence of correlation of results through the analysis of a sample of known concentration which is traceable to national standards (proficiency testing), independent analysis or use of a suitable interlaboratory comparison.

22.4.1.1 Records

Initial instrument calibration records includes calculations, integrations, acceptance criteria, and associated statistics referenced in the applicable test method SOP either in the data packet or in Teklab LIMS.

Sufficient raw data records are collected to allow reconstruction of the initial instrument calibration. These include, at a minimum, calibration date, test method, instrument, analysis date, analyte names, analysts signature or initials, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration.

Calibration date and expiration criteria is documented in the applicable SOP for equipment requiring calibration, where practicable (see Section 22.1).

22.4.1.2 Number of Standards and Concentrations:

This section dictates the general calibration procedures and frequency for all instrumentation at Teklab. The number of standards required for calibration is indicated and the minimum correlation factor (R) for the curve is indicated in the applicable SOP.

For instrumentation where single point calibration is recommended by manufacturer's instructions, such as with some ICP and ICP/MS technologies (with a zero and single point calibration), the following apply:

1) Prior to the analysis of samples, the zero point and single point calibration are analyzed and the linear range of the instrument are established by analyzing a series of standards, one of which must be at the lowest quantitation level. Sample results within the established linear range will not require data qualifier flags.
2) Zero blank and single point calibration standards are analyzed with each analytical batch for methods where they are specified.
3) A standard corresponding to the limit of quantitation must be analyzed with each analytical batch and must meet established acceptance criteria when using single point plus zero blank calibrations.
4) The linearity of single point plus zero blank calibrations is verified at a frequency established by the method or the manufacturer.

If the reference or mandated method does not specify the number of calibration standards, the minimum number of points for establishing the initial instrument calibration shall be three (TNI 2009 M1V4 Section 1.7.1.1j). When not specified by the test method, the appropriate number of standards for use in the initial calibration curve is determined using the following procedure:

Determine a percent relative standard deviation (%RSD) of:

- The analysis of a minimum of seven replicate measurements of a standard with a concentration at one to three times the MDL; or

- The response factors (internal standard calibration) or calibration factors that cover the expected calibration range.

Determine the minimum number of calibration standards to be used in the initial calibration curve by correlating the %RSD with the number of required calibration standards:

%RSD	**Number of Calibration Standards**
0 -<2	1**
2 -<10	3
10-<25	5
>25	7

**Assumes linearity through the origin (0,0).
For analytes for which there is no origin (such as pH), at least a two point calibration curve is used.

The number of calibration standards (as determined from the applicable SOP) and a blank shall be used to generate the initial calibration curve of the approved test method.

If the calibration curve is not linear as defined in subsection 22.4.1.3(d) and the approved test method allows for the use of non-linear calibration curves; additional calibration standards shall be used to define the calibration.

If the approved test method specifies the generation and use of a calibration curve, all sample results shall be reported from sample analyses within the range of the calibration curve, except, when the approved test method specifically allows otherwise (for example ICP analysis above the highest calibration standard concentration but within the linear dynamic range as established by the laboratory pursuant to the applicable approved test method). See 22.4.1.2(1-4) for exception procedures.

The lowest calibration standard is the lowest concentration for which quantitative results can be reported without qualification. The lowest calibration standard is at or below the Practical Quantitation Limit (PQL) and is greater than the Method Detection Limit (MDL). Results that are less than the PQL are considered to have increased uncertainty, and are reported with “J” qualifiers as defined in the case narrative of the final report.

The highest calibration standard is the highest concentration for which quantitative results can be reported. Data reported exceeding the highest calibration standard without dilutions is considered to have increased uncertainty and are reported with "E" qualifiers as defined in the case narrative of the final report.

22.4.1.3 Evaluation, Verification and Corrective Action

All initial instrument calibrations are verified with a standard obtained from a second source traceable to a national standard when commercially available. If a second source is not available, a standard prepared from a vendor certified different lot may be used.

a) ICV check standards are prepared at the concentrations specified in the approved test method. If the approved test method does not specify the concentration for the ICV check standard, a concentration at 10% to 50% of the maximum calibration range is used. Exceptions may be made for multi analyte tests in which the ICV is prepared using standard mixes.

b) The laboratory utilizes the ICV check standards' acceptance criteria specified in the approved test method. If the approved test method does not specify the ICV acceptance criteria, the results of the analyses of the ICV check standard shall be within CCV criteria, or within 15% of the true value or within the 95% confidence interval determined from a minimum of 20 analysis of the ICV check standards.

If the analysis of the ICV check standard fails to meet the acceptance criteria specified in subsections 22.4.1.3(b) above, the laboratory shall either:

c) Suspend sample analysis and take corrective action to be followed immediately by a reanalysis of the ICV check standard; or

d) Immediately reanalyze the ICV check standard; and evaluate the subsection 22.4.1.3(c) ICV check standard reanalysis results as follows:

- The laboratory may continue sample analysis for the analytes for which the results of the reanalysis of the ICV check standard meet the acceptance criteria specified in subsection 22.4.1.3 (b).
- The laboratory shall terminate sample analysis or reject sample analysis data for the analytes for which the results of the reanalysis of the ICV check standard fail to meet the acceptance criteria specified in subsection 22.4.1.3 (b).
- The laboratory may proceed with sample analysis for the analytes for which the acceptance criteria were not met only after the establishment and verification of a new initial calibration curve pursuant to this Section.
- In the instance samples were ran after a failing ICV, and re-analysis is impossible, any data reported with a failing ICV shall be reported with data qualifying codes.

Quantitation is always determined from the initial calibration unless the test method or applicable regulations require quantitation from the continuing instrument calibration verification.

All initial calibration curves are subject to a calibration linearity test.

e) The calibration linearity shall be determined by the following as directed in the test method:

- *A linear regression analysis of the calibration curve;*
- *Determining the %RSD of the response factors (internal standard calibration); or*
- *Determining the %RSD of the calibration factors (external standard calibration).*

f) The initial calibration curve is considered linear when:

- *The correlation coefficient from the linear regression analysis is 0.995 or greater (Unless otherwise stated in the method)*
- *The %RSD of the response factor is 15% or less; or*
- *The %RSD of the calibration factors is 30% or less.*

g) If the initial calibration curve is linear as determined pursuant to:

- *The correlation coefficient in 22.4.1.3 (f), the laboratory utilizes the linear regression to determine the analytical results;*
- *The response factor in 22.4.1.3 (f), the laboratory utilizes the average response factor to determine the analytical result; or*
- *The calibration factor in 22.4.1.3(f), the laboratory utilizes the average calibration factor to determine the analytical results.*

Corrective actions are performed when the initial calibration results are outside acceptance criteria. Calibration points are not dropped from the middle of the curve unless the cause is determined and documented. If the cause cannot be determined, the calibration curve is re-prepared. If the low or high calibration point is dropped from the curve, the working curve is adjusted and sample results outside the curve are qualified. See Section 11 – "Control of Nonconforming Environmental Testing".

22.4.2 Continuing Instrument Calibration

22.4.2.1 Records

Sufficient raw data records are retained to allow reconstruction of the continuing instrument calibration verification. Continuing instrument calibration verification records connect the continuing verification date to the initial instrument calibration. The laboratory documents all activities related to calibration and standardization as specified

Where appropriate, the laboratory has manual integration procedures (SOP 4026) that are adhered to when evaluating calibration data.

22.4.2.2 Frequency

The laboratory analyzes a continuing calibration blank when required by the test method. The analysis of the CCV check standard must meet the acceptance criteria specified in 22.4.2.3.1

The laboratory initially analyzes a CCV check standard;

1. At the approved test method specified concentration, or if the approved test method does not specify the concentration for the CCV check standard, the concentration shall be at 25% to 50% of the maximum of the calibration range. Exceptions may be made for multi analyte tests in which the ICV is prepared using standard mixes.

2. The laboratory shall analyze a CCV check standard at the beginning and end of each analytical batch. Further frequency of the CCV shall be determined by the SOP for that particular test. For instruments using internal standards, the laboratory shall analyze a CCV check standard at the beginning of each analytical batch.
3. A CCV must be repeated whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria.
4. A CCV must be repeated if the time period for calibration or the most previous calibration verification has expired.

22.4.2.3 Evaluation, Verification and Corrective Actions

To verify the continued acceptability of the initial calibration, the laboratory prepares and performs the analysis of a CCV check standard for all instrumentation and equipment according to the following procedure:

a) The laboratory utilizes a CCV check standard prepared from the initial calibration curve standards or from a second source material.

b) The laboratory prepares a CCV check standard at a concentration within the range of the initial calibration standards.

c) Whenever the laboratory does not prepare an initial calibration curve on the day of analysis, the laboratory verifies the integrity of the initial calibration curve prior to sample analysis, by analyzing continuing calibration verification with each analytical batch.

22.4.2.3.1 Acceptance Criteria

The laboratory utilizes the CCV check standards' acceptance criteria specified in the approved test method SOP. If the approved test method does not specify the CCV acceptance criteria, the CCV check result shall be within 15% of the true value or within the 95% confidence interval determined from a minimum of 20 analysis of the CCV check standard at a single concentration.

22.4.2.3.2 Acceptance Criteria failure

If the analysis of the CCV check standard fails to meet the acceptance criteria specified above the laboratory suspends sample analysis and makes routine corrective action to be noted on the raw data package and followed by an immediate reanalysis of the CCV check standard. Evaluate the check standard reanalysis results as follows:

a) The laboratory continues sample analysis for the analytes for which the results of the second analysis of the CCV check standard meet the acceptance criteria specified in subsection 22.4.2.3.1.
b) The laboratory terminates sample analysis or rejects sample analysis data for the analytes for which the results of the second analysis of the CCV check standard fail to meet the acceptance criteria specified in subsection 22.4.2.3.1.
c) The laboratory may proceed with sample analysis for the analytes for which the acceptance criteria were not met only after the establishment and verification of a new initial calibration curve pursuant to this section.

22.4.3 Unacceptable Continuing Instrument Calibration Verifications

If routine corrective action for continuing instrument calibration verification fails to produce a second consecutive (immediate) calibration verification within acceptance criteria, then a new calibration is performed or acceptable performance is demonstrated after corrective action with two consecutive calibration verifications.

For any samples analyzed on a system with an unacceptable calibration, some results may be useable under the following conditions:

a) If the acceptance criteria are exceeded high (high bias) and the associated samples are below detection, then those sample results that are non-detects may be reported as non-detects.

b) If the acceptance criteria are exceeded low (low bias) and there are samples that

exceed the maximum regulatory limit, then those exceeding the regulatory limit may be reported.

Section 23 – Standards and Reagents

(TNI V1:M2 – Section 5.6)

Measurement quality assurance comes in part from traceability of standards to certified materials.

All equipment used affecting the quality of test results are calibrated prior to being put into service and on a continuing basis (see Section 22 "Calibration Requirements"). These calibrations are traceable to national standards of measurement where available.

If traceability of measurements to SI units is not possible or not relevant, evidence for correlation of results through interlaboratory comparisons, proficiency testing, or independent analysis is provided.

23.1 Reference Standards

Reference standards are standards of the highest quality available at a given location, from which measurements are derived (e.g. ASTM Class 1 weights, NIST traceable reference thermometers).

Reference Standards, such as ASTM Class 1 weights, are used for calibration only and for no other purpose. Reference standards, such as ASTM Class 1 weights, are calibrated by an entity that can provide traceability to national or international standards. The following reference standards are sent out to be calibrated to a national standard as indicated in Section 22 – "Calibration Requirements"

23.2 Standards and Reagents

Reference materials, where commercially available, are traceable to national standards of measurement, or to Certified Reference Materials, usually by a Certificate of Analysis.

Upon receipt, all reagents and standards shall be inspected, receipt dated, initialed, the lot number shall be recorded and an expiration date shall be assigned. No reagents or standards shall be used beyond their expiration date without verification of their continued validity.

All reagents and standards shall be of adequate quality to sustain confidence in the laboratory's test, as specified by the SOP for each analytical method. Laboratory supervisors are responsible for scanning and linking all Certificates of Analysis of standards into Teklab LIMS. Where no independent assurance of the quality of reagents or standards is available, the standard or reagent must be shown to produce acceptable results for the test method, within quality control limits of the test, before onset of sample analysis. See SOP1250 "Reagents and Standards" for more information.

23.3 Transport and Storage

The laboratory handles and transports reference standards and materials in a manner that protects the integrity of the materials. Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments or materials.

Reference standards and materials are stored according to manufacturer's recommendations, method SOP requirements and separately from samples.

23.4 Labeling

The laboratory has procedures for purchase, receipt and storage of standards, reagents and reference materials. Purchase procedures are described in Section 7 – "Purchasing Services and Supplies".

All containers of prepared standards and reagents are labeled with a unique identification number (using the LIMS identification system) and an expiration date (where applicable). This information is documented in the LIMS and all records retained.

23.4.1 Stock Standards and Reagents

The laboratory retains records supplied by the manufacturer/vendor, which include the manufacturers' Certificate of Analysis or purity for standards, the date of receipt, recommended storage conditions and an *expiration date after which the material shall not be used unless its reliability is verified by the laboratory. These documents are retained for the same length of time as that required for the retention of documentation associated with the analytical results for which the standards or reagents were used.

If reference materials cannot be purchased with a Certificate of Analysis, the laboratory produces evidence of correlation of results through the analysis of a sample of known concentration which is traceable to national standards (proficiency testing), independent analysis or use of a suitable interlaboratory comparison.

Records shall include:

- the manufacturer/vendor name (or traceability to purchased stocks or neat compounds)
- the manufacturer's Certificate of Analysis or purity (if supplied)
- the date of receipt
- recommended storage conditions

This information is logged into the applicable section of the LIMS. Certificates of Analysis for Standards are scanned and linked to the LIMS by the applicable department or a member of the quality department.

In methods where the purity of reagents is not specified, analytical reagent grade is used. If the purity is specified, that is the minimum acceptable grade**.** Purity is verified and documented according to Section 7 – "Purchasing Services and Supplies".

*If the original container does not have an expiration date provided by the manufacturer or vendor, it is not required to be labeled with an expiration date.

23.4.2 Prepared Standards and Reagents

Preparation of standard solutions are documented to include; date of preparation, expiration date (expiration of the standard shall not exceed the preparation date of the parent standard or stock solution), concentration of the parent standard or stock solution, concentration of standard working solution and the initials of the person preparing the solution. All standard solutions are prepared using class A or equivalent glassware and analytical balances. Standard concentrations (or a dilution thereof) are checked using an independent reference standard.

Reagent purity is checked through the use of Laboratory Control Blanks. Any contamination discovered in a reagent will be noted and that lot of reagent shall not be used.

The laboratory documents and maintains records concerning the receipt, use and traceability of analytical reagents and standards, including at a minimum:

- Verification of standards traceable to national standards. If traceability to a national standard is not possible, the lab demonstrates by appropriate means (e.g. analyses of PT samples) that the instrumentation/equipment is properly calibrated;
- Certificate of the origin, purity and traceability of all standards. These records include the date of receipt, storage conditions, and the date of opening.
- Procedures to ensure the traceability of working and intermediate standards to purchased stock standards or neat compounds which include the date of preparation and preparer's initials; and
- Procedures to clearly identify all prepared reagents and standards, including preparation date, concentrations, and preparer's initials;

See Section 5 of this Quality Manual for more information on control of records.

Section 24 - COLLECTION OF SAMPLES

(TNI V1:M2 – Section 5.7)

Regardless of the laboratory's level of control over sampling activities, all the requirements of this section are essential to ensure sample integrity and valid data and shall be followed by the laboratory. Sampling performed by Teklab, Inc. is governed by SOP 1150. Field sampling and any laboratory sub-sampling necessary to obtain sample aliquots for testing are covered in SOP 1150.

24.1 Sampling Containers and Kits

The laboratory offers clean sampling containers and kits for use by clients.
See the following Teklab SOPs for more information:
1081 Sample Kit Preparation
1082 Bottle Certification
1083 5035 Sampling Kit Preparation
1090 Landfill Sample Bottles

24.2 Sampling Plan

The laboratory uses sampling plans provided by clients or prepared in consultation with the client. The plan must include any factors that must be controlled to ensure the validity of the test. Sampling plans and written sampling procedures are used for sampling substances, materials or products for testing. The plan and procedures are made available at the sampling location.

The laboratory's procedures for dealing with non-conformances are used when the client requests any deviations from the sampling plan or sampling procedures. The requests are documented and included in the final test report.

See the following Teklab SOPs for more information:
1150 Sampling Instructions
1151 Groundwater Sampling

Section 25 – Sample Receipt and Storage

(TNI V1:M2 – Section 5.8 and Section 1.7 of Technical Modules TNI V1: M 3-7)

This section applies to samples received by Teklab and will be used to guide clients in sampling requirements specified in the "Federal Register, 40 CFR Part 136, Table II". Teklab does not reuse sample containers at this time except for air. See SOP 6000 SiloniteTM canisters for cleaning procedures for air containers.

25.1 Sample Receipt

When samples are received at the laboratory, the chain-of-custody is reviewed, the condition is documented, samples are given unique identifiers, and they are logged into the sample tracking system.

25.1.1 Chain of Custody

A customer service specialist or their designated representative indicates receipt of samples by signing the accompanying custody form. The supervisor or project manager reviews the signed form. The original signed custody form becomes part of the final data package that is reported to the client. The laboratory scans and files a copy of the signed custody form along with the final report as a permanent record of the sample receipt.

25.1.2 Legal/Evidentiary Chain of Custody

The laboratory has procedures for legal chain of custody services. If samples are noted as being used for legal/evidentiary purposes, special chain of custody procedures are put into place by the laboratory. See Sop1065 "Legal or Evidentiary Custody" for more information.

25.2 Sample Acceptance

Procedures for opening shipping containers and examining samples are provided in SOPs 1110 "Sample Pickup and Delivery" and 1070 "Sample Acceptance".

Teklab has a sample acceptance policy that is made available to sample collection personnel (See SOP 1070 Sample Acceptance). It emphasizes the need for use of water resistant ink, providing proper documentation (to include sample ID, location, date and time of collection, collector's name, preservation type, sample type and any special remarks about the sample), labeling of sample containers to include a unique sample ID, use of appropriate containers, adherence to holding times, and sample volume requirements. In addition the laboratory has nonconformance/corrective action procedures to handle samples that do not meet the requirements above or show signs of damage, contamination or inadequate preservation. Data will be appropriately qualified where samples are reported that do not meet sample acceptance requirements.

On samples receipt the laboratory checks for the conditions above and logs the applicable information into the LIMS Sample Checklist. This checklist becomes part of the final report. Criteria regarding preservation, holding time and sample volume requirements can be found in 1000 series SOP Appendix B

If these conditions are not met, the laboratory follows SOP1070 and the client is contacted prior to any further processing, then

1) the sample is rejected as agreed with the client,
2) the decision to proceed is documented and agreed upon with the client,
3) the condition is noted on the Chain of Custody form and/or lab receipt documents, and;
4) the data are qualified in the case narrative or sample checklist of the final report.

25.2.1 Preservation Checks

See 1000 series SOP Appendix B for information on preservation requirements.

25.3 Sample Identification

The customer service specialists use LIMS to maintain an electronic log book to record, for each sample, the person delivering the sample, the person receiving the sample, the date and time received, source of sample, sample identification and a unique laboratory ID code. The laboratory ID code is used as the link that associates the sample with the field ID code, the date and time of sample collection, the date and time of sample receipt, the requested analysis (including applicable approved test method numbers), any comments resulting

from inspection for sample rejection, and other related laboratory activities. The laboratory ID code is transferred to all sub-samples, extracts, and digestates. The custodians document the condition of the sample upon receipt (i.e. unsealed, broken container, etc.). A standardized format is used for the electronic log-in book.

Each sample container is identified by affixing a durable label which specifies the unique LIMS generated laboratory ID code for each container. The LIMS generated laboratory ID code includes the work order number, the lab number and the container identifier.

A work order number is generated by the LIMS system. The first two digits in the work order number indicate the year the sample was received by the laboratory, the third and fourth digit indicate the month received, the remaining four digits indicate the consecutive COC number for the month. Following the work order number, LIMS generates a consecutive lab number for each sample on the COC preceded by a dash. The lab number is followed by a letter to uniquely identify each sample fraction received. When 2 containers or vials are received for the sample fraction, the bottle labels are numbered (i.e. 1 of 2, 2 of 2) so that the analyst can document from which sample container or vial any sub-sample was taken.

All documentation received regarding the sample, such as memos or chain of custody, are scanned and retained with the final report on the Teklab Inc Server.

25.4 Sample Aliquots / Subsampling

In order for analysis results to be representative of the sample collected in the field, the laboratory has subsampling procedures. See SOP1150 for more information.

25.5 Sample Storage

Clean, dry, isolated cabinets and/or refrigerators that can be securely locked from the outside are designated as a "sample storage security areas". In the Teklab Air Laboratory, and the Kansas, Downers Grove and Springfield Service Centers, the entire facility is considered secure. The laboratory limits access to authorized laboratory personnel only. During operating hours, all samples remain in the laboratory secure areas. During non-operating hours, all samples are locked in the storage refrigerators or cabinets in the laboratory secure areas. The laboratory controls and documents access to all samples and sub samples designated as litigation samples by the client. Details can be found in SOP 1065 “Legal or Evidentiary Custody“.

The client must inform the laboratory of any heat-sensitive, light-sensitive, radioactive, or other sample materials having unusual physical characteristics or that require special handling. The custodian shall ensure samples are properly stored and maintained prior to analysis.

The custodian distributes samples to the laboratory supervisor or the appropriate laboratory cooler (or his or her representative) responsible for the lab analysis. Sample transfers within the laboratory are monitored by a sample custodian using the LIMS sample

tracking system. Where possible, distribution of samples to the analyst performing the analysis must be made by the custodians.

Laboratory personnel are responsible for the care and custody of the sample once they receive it. They must be prepared to testify that the sample was in their possession and in view or secured in the laboratory at all times from the moment it was received from the custodian, until the completion of the analysis.

Drinking water Bacteria samples are delivered to the Microbiology laboratory immediately upon receipt. They are then logged into the LIMS, prior to analysis. Aqueous and solid samples to be analyzed for Fecal Coliform are stored separately from potable water samples.

The laboratory provides sample storage facilities that prevent cross-contamination of samples and meet the conditions specified by preservation protocols. Samples are stored away from all standards, reagents, food and other potentially contaminating sources. Sample fractions, extracts, leachates and other sample preparation products are stored according to this section, SOP1120 or according to specifications in the approved test method. The laboratory verifies that cross-contamination between samples has not occurred through the examination of storage areas or through the review of analytical data on laboratory blanks that are stored with samples.

Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, must be returned to the custodian. The returned, tagged sample/s should be retained in the custody room for a period of 30 days for aqueous and drinking water samples and no less than 2 weeks for solids and special wastes. Solids and special wastes are transferred to a storage shed where they are held for an additional 4 weeks when more room is needed in the walk in cooler (unless otherwise requested by the client). Volatile air samples are retained for three days after the final report is issued to the client and then disposed of. Litigation samples are retained until permission is given from the proper authority (See SOP1065 “Legal or Evidentiary Custody” for more information on Litigation Samples).

See SOP1120 “Sample Storage, Retention and Disposal” for more information.

25.6 Sample Disposal

Teklab complies with all applicable federal, state and local laws concerning the handling and disposal of hazardous waste. Teklab also complies with all applicable laws concerning the generation of air pollutants. All laboratory samples are disposed of according to Federal, State and local regulations. Procedures are described in SOP1120 “Sample Storage, Retention and Disposal” and SOP1130 “Waste Disposal” for the disposal of samples, digestates, leachates, and extracts. Records for sample disposal are kept indefinitely

25.7 Sample Transport

Samples that are transported under the responsibility of the laboratory, where necessary, are done so safely and according to storage conditions. This includes moving bottles within

the laboratory. Appropriate DOT shipping instructions will be available to clients upon request. Specific safety operations are addressed outside of this document.

Sample shipping procedures are described in SOP 1100 Subcontracting and Shipping.

Section 26 - QUALITY ASSURANCE FOR ENVIRONMENTAL TESTING

(TNI V1:M1, V1:M2 – Section 5.9 and Section 1.7 of Technical Modules TNI V1: M 3-7)

26.1 DEFINITIONS

Quality Control Indicators (QCI); such as Trip Blanks (TB), Duplicates (Dup), Initial Calibration Verification (ICV), Continuing Calibration Verification (CCV), Laboratory Control Blanks (LCB), Laboratory Control Samples (LCS), Standard Reference Materials (QC sample) and Matrix Spikes/Matrix Spike Duplicates (MS/MSD) will be analyzed to assess the quality of the data resulting from the field sampling program and in-house analysis.

Trip blanks (Equipment Blanks):
A trip is used to identify contamination from transport, shipping and site conditions. Trip blanks are analyte-free water taken to the field and returned to the laboratory unopened for analysis, to determine if contamination has occurred. Equipment blanks are used to identify contamination from sampling procedures. Equipment blanks are opened in the field, poured appropriately over or through the sample collection device and brought in for analysis to determine if contamination has occurred.

Field Blanks:
A Field Blank is exposed to the same field conditions as the sample, opened in the field. Its purpose is to assess the potential for field contamination.

Duplicate samples:
Analyzed to check for sampling and analytical reproducibility. Field duplicates are taken during sample collection. Internal duplicates are analyzed in the laboratory by splitting the sample and analyzing each split as an independent sample. See applicable SOP for frequency of matrix spike duplicates by analysis.

LCB (laboratory control blanks) or **MBLK** (method blanks):
A LCB is used to check contamination in the laboratory and is taken through the entire analytical procedure. The method blank consists of a matrix that is similar to the associated samples and is known to be free of the analytes of interest. These samples are used to verify the purity of all chemicals and reagents used in the methodologies and to prove the absence of contamination during the analytical procedure.

LCS samples (Laboratory control samples)**:**
The LCS is prepared from a matrix that is similar to the associated samples known to be free of the analytes of interest and spiked with known and verified concentrations of analytes. This sample is then taken through the entire analysis to determine batch acceptance.

QC samples:
QC samples are purchased from an independent source to verify analytical procedures and calibrations. All QC samples must be NIST traceable reference materials, when available.

If a QC sample is not taken through the entire sample preparation procedure and is used for calibration verification (ex. GFAA), a LCS which has been taken through the entire procedure must also be analyzed.

Matrix spikes:
These provide information about the effect of the sample matrix on the preparation and measurement methodology. All matrix spikes and matrix spike duplicates are hereafter referred to as MS/MSD samples. These samples are always run with another aliquot of the sample that is not spiked. Spiking a sample tells us what effect the sample matrix (i.e. aqueous, solid, non-aqueous liquid) has on the parameter being measured. Sometimes the sample matrix will hide a parameter; a matrix spike will help identify this effect by showing a low recovery. Because matrix spikes give more information about the sample and its matrix, they are preferred to running duplicates. Some analysis (pH and Temp for example) do not lend themselves to matrix spikes very easily, therefore some analysis do not use matrix spikes (inorganic/physical analysis only).

Batch:
Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents.

Prep Batch:
Composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours

Analytical Batch:
Composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples.

TCLP METALS AND ORGANICS**:** Every unique TCLP sample matrix will be run both with and without matrix spikes, under direction of US EPA SW-846. However, as generally accepted laboratory practice, Teklab will not run TCLP matrix spikes on every sample, unless requested by the client. The frequency of matrix spiking (detailed in the applicable SOP) will be followed unless otherwise requested.

NOTE: Some clients may request specific types of quality control analysis. Those instances will be handled on a case by case basis.

26.2 Essential Quality Control Procedures

Teklab Inc has procedures for monitoring the validity of the testing it performs. The qualities of test results are recorded in such a way that trends are detectable, and where practicable, are statistically evaluated. To evaluate the quality of test results, the laboratory utilizes various

evaluation aids such as certified reference materials, proficiency testing samples and control charting.

Quality control data are analyzed and when found to be outside pre-defined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Data associated with quality control data outside of criteria and still deemed reportable will be qualified so the end user of the data may make a determination of the usability of the data - see Section 27 – "Reporting of Results".

The quality control procedures specified in test methods are followed by laboratory personnel. The most stringent of control procedures is used in cases where multiple controls are offered. If it is not clear which is the most stringent, that mandated by test method or regulation is followed.

Teklab utilizes the quality control procedures set forth in this section if the approved test method does not specify any quality control procedures or the quality control procedures contained in the approved test method are less stringent.

Teklab assesses and evaluates the results of all quality control procedures on an on-going basis.

A) Written procedures to ensure that all results from all quality control procedures are reviewed and the decision made to accept, reject, or qualify sample data before the data is reported.
B) Written criteria for accepting, rejecting, or qualifying sample data based on each quality control procedure.
    i) Teklab uses the acceptance criteria contained in the approved test method for evaluating the results of each of the quality control procedures and for accepting, rejecting, and qualifying sample data.
    ii) If the approved test method does not specify the criteria for evaluating the results of each of the quality control procedures and for accepting, rejecting, and qualifying data, Teklab establishes written criteria.
C) If a quality control procedure results in the laboratory rejecting or qualifying sample data, the laboratory may implement corrective actions. When analyzing reference materials, the laboratory uses the acceptance criteria supplied by the manufacturer.
D) The laboratory completes corrective actions and maintains written records as required in Section 5 of this manual.

Written procedures to monitor routine quality controls including acceptance criteria are located in the test method SOPs, except where noted, and include such procedures as:

- use of laboratory control samples and blanks to serve as positive and negative controls for chemistry methods;
- use of laboratory control samples to monitor test variability of laboratory results;
- use of calibrations, continuing calibrations, certified reference materials and/or PT samples to monitor accuracy of the test method;

- measures to monitor test method capability, such as limit of detection, limit of quantitation, and/or range of test applicability, such as linearity;
- use of regression analysis, internal/external standards, or statistical analysis to reduce raw data to final results;
- use of reagents and standards of appropriate quality and use of second source materials as appropriate;
- procedures to ensure the selectivity of the test method for its intended use;
- measures to assure constant and consistent test conditions, such as temperature, humidity, etc., when required by test method;

26.3 Internal Quality Control Practices

Analytical data generated with QC samples that fall within all prescribed acceptance limits indicate the test method is deemed to be in control.
QC samples that fall outside QC limits indicate the test method are deemed to be out of control (nonconforming) and that corrective action is required and/or that the data are qualified (see Section 11 – "Control of Nonconforming Environmental Testing Work" and Section 13 - "Corrective Actions").

Detailed QC procedures and QC limits are included or referenced in test method standard operating procedures (SOPs), or where unspecified in the SOPs, are detailed in the method.

See applicable SOP for Duplicate and Matrix Spike concentrations and frequency.

26.3.1 General Controls

Teklab follows the quality control procedures and quality control indicators (QCI) specified below:

Laboratory Control Blank (LCB)
A minimum of 1 laboratory control blank (LCB) is analyzed with each preparation batch of environmental samples and carried through the entire analytical process. LCBs are not required for approved test methods, including but not limited to: pH, temperature and conductivity, for which method blanks are not appropriate. For analysis in which no separate preparation method is used, LCBs are prepared at the beginning each batch and once every 20 samples in between.

A) A batch of drinking water sample data meets the requirements of this section only when the method blank does not contain an analyte of interest at a concentration greater than the MDL.

B) A batch of environmental sample data, except for drinking water sample data, meets the requirements of this section when the method blank does not contain an analyte of interest at a concentration greater than the highest of the following:

i) The MDL or PQL whichever the client requires for the reporting limit
ii) 10% of the regulatory limit for that analyte, or
iii) 10% of the measured concentration for that analyte in any environmental sample in the batch.

C) The provisions of subsection 26.2.1 Laboratory Control Blank(B) do not apply in those instances where the method blank criteria have not been met and there are non-detect results for the corresponding analyte in the environmental samples associated with the method blank. In such instances, the non-detect results may be reported with a comment in the sample narrative.

D) The following corrective actions are to be taken when (26.2.1 Laboratory Control Blank)(A), (B), or (C) above are not met:
i) The run of analysis is terminated (and no sample results are reported);
ii) The source of the contamination is identified, eliminated and documented;
iii) The samples are reanalyzed and results are reported only after the conditions of (26.2.1 Laboratory Control Blank)(A), (B) or (C) above are met.
iv) If corrective actions cannot be taken (i.e. insufficient sample), the results may be reported with the appropriate qualifiers.

Matrix spikes (MS)

Matrix Spikes are performed at a rate of one per 20 or fewer environmental samples per matrix type, per sample extraction or preparation procedure.

A) The laboratory utilizes the spiking analytes specified in the approved test method, except when the approved test method indicates that all method analytes are to be matrix spiked. In such cases the laboratory shall spike the target analytes for the sample or any client requested analytes.

B) If there are no specified spiking analytes, the laboratory spikes per the following:
i) For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike or spikes are chosen that represent the chemistries and elution patterns of the components to be reported.
ii) For those test methods that have extremely long lists of analytes, a representative number are chosen using the following criteria for choosing the number of analytes to be spiked.
a. For methods that include 1-10 targets, all components are spiked;
b. For methods that include 11-20 targets, at least 10 or 80%, whichever is greater are spiked;
c. For methods with more than 20 targets, 16 or more components are spiked.

C) The laboratory selects samples on a rotating basis to receive matrix spike analysis from among various client samples, waste streams, monitoring locations

and other applicable locations. Matrix spikes are selected randomly, unless specified by the client.

D) As is required in section 10 of this manual, the procedure used to select the sample for matrix spike analysis must be documented.

E) Matrix spikes are not required for approved test methods in which materials for matrix spiking are not available, including but not limited to: total suspended solids, total dissolved solids, total volatile solids, flash point, reactivity, pH color, odor, temperature, dissolved oxygen and turbidity.

F) Matrix spike recoveries are within the acceptance limits when:
   i) They are within the limits given in the approved method (when available), laboratory established limits, or those given by laboratory generated control charts, or
   ii) The matrix spike concentration is less than 20% of the sample concentration, or
   iii) a diluted sample, which is bench spiked, shows a spike recovery within the acceptance criteria given in (F)(i) above. (Note: the reporting limit must be elevated by the dilution factor.)

G) The following corrective actions are taken when (F)(i), (ii), (iii) above are not met:
   i) The samples are reanalyzed, if necessary, and results are reported only after the conditions of (F)(i), (ii) or (iii) above are met, or
   ii) Sample results are qualified, when reporting to customer, as showing adverse matrix effects.

Matrix spike duplicates (MSD)/sample duplicates

MSDs or Sample duplicates are performed at a rate of one per 20 or fewer environmental samples per matrix type, per sample extraction or preparation procedure.

A) Matrix spike duplicates are performed on the same environmental sample chosen for matrix spike analyses.

B) Samples are selected on a routine basis to receive sample duplicate analyses from among various client samples, waste streams, monitoring locations and other applicable locations. Matrix spike duplicates and/or matrix duplicate samples are selected randomly, unless specified by the client.

C) The laboratory documents, as required in section 10 of this manual, the procedure used to select the sample for matrix spike duplicates or sample duplicate analysis.

D) Relative Percent Differences (RPD) are within the acceptance limits when they are within the limits given in the approved method or those given by laboratory generated control charts. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.

E) The following corrective actions are to be taken when (D) above is not met:

i) The sample is reanalyzed, if necessary and results are reported only after the conditions of (D) above are met.

ii) Sample results for matrix spike duplicates or sample duplicates RPD, which do not meet the acceptance criteria of (D), are to be qualified when reporting to the customer as showing adverse matrix effects or problems with the samples composition.

Laboratory control samples (LCS)

LCSs are analyzed at a minimum of one per preparation batch, except for analytes for which spiking solutions are not available such as, total volatile solids, pH, color, odor, temperature, dissolved oxygen or turbidity. In those instances for which no separate preparation method is used, the batch is defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples. Air Testing: If a calibration solution must be used for the LCS, the client shall be notified prior to the start of analysis. Also the concentration of the LCS shall be relevant to the intended use of the data and either at a regulatory limit or below it.

A) The laboratory may use the results of these LCS analyses to determine batch acceptance.

B) The LCS is a quality system matrix, known to be free of analytes of interest, spiked with a known and verified concentration of analytes. All analyte concentrations must be within the calibration range of the methods. The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components, the laboratory shall spike per the following:

i) For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike or spikes are chosen that represent the chemistries and elution patterns of the components to be reported.

ii) For those test methods that have extremely long lists of analytes, a representative number are chosen. The analytes selected shall be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be spiked.

a. For methods that include 1-10 targets, all components are spiked;
b. For methods that include 11-20 targets, at least 10 or 80%, whichever is greater are spiked;
c. For methods with more than 20 targets, 16 or more components are spiked.

C) The laboratory may use the matrix spike samples as specified in subsection 26.2.1 Matrix Spikes (A) as a LCS when the matrix spike acceptance criteria are as stringent as the LCS acceptance criteria. However, if the laboratory prepares a LCS, the laboratory shall analyze the LCS and use the results to determine batch acceptance. The laboratory shall not use the analyses of matrix spike samples as specified in subsection 26.2.1 Matrix Spikes (A) to override, ignore, or replace an LCS analysis that fails to meet the acceptance criteria. (If there is insufficient sample for reanalysis and the client is unable to re-sample, the data must be reported to the client with the appropriate qualifiers indicating the QC

deviation. In control matrix spike and surrogate recoveries will help support the batch acceptance).

D) The analytes must be obtained from a second source if the LCS is to be used to verify the instrument calibration.

E) LCS recoveries are within the acceptance limits when they are within the limits given in the approved method (when available), laboratory established limits, those given by laboratory generated control charts, or client specified assessment criteria.

F) The following corrective actions are to be taken when (E) above is not met:
   i) The run of analysis is terminated (and no sample results are reported);
   ii) The reason for the unacceptable recovery is identified, eliminated and documented;
   iii) The sample batch is reanalyzed and results are reported only after the conditions of (E) above are met.
   iv) If corrective actions cannot be taken (i.e. insufficient sample), the clients involved are contacted and the samples are recollected or the results are reported with the appropriate qualifiers, according to the client's instructions.

G) If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control; therefore, corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits determine when corrective action is needed. A ME is defined as being beyond the LCS control limit (3 standard deviations), but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean. Marginal exceedances must be random. If the same analyte exceeds the LCS control limit consecutively, it is an indication of a systemic problem. Marginal exceedance limits can be determined by using the control charting feature in Teklab LIMS. It is the responsibility of the laboratory supervisor utilizing a ME allowance, to monitor the LIMS data and assure random behavior. The number of allowable marginal exceedances is as follows:
   1. >90 analytes in LCS, 5 analytes allowed in ME of the LCS control limit;
   2. 71-90 analytes in LCS, 4 analytes allowed in ME of the LCS control limit;
   3. 51-70 analytes in LCS, 3 analytes allowed in ME of the LCS control limit;
   4. 31-50 analytes in LCS, 2 analytes allowed in ME of the LCS control limit;
   5. 11-30 analytes in LCS, 1 analytes allowed in ME of the LCS control limit;
   6. <11 analytes in LCS, 0 analytes allowed in ME of the LCS control limit.

Surrogates

Surrogate compounds are added to all samples, standards, and blanks whenever possible, when conducting analysis by approved test methods utilizing organic chromatography.

A) The compounds specified are chosen to represent the various chemistries of the target analytes in the method or the measurement quality objectives. They are often specified by the mandated method and are deliberately chosen for their

being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.

B) The surrogate recoveries are within the acceptance limits when they are within the limits given in the approved method or, if not specified, the limits given by the laboratory generated control charts.

C) The following corrective actions are to be taken when (B) above is not met:

i) If the surrogates are out of control for a method blank or LCS, the associated batch must be evaluated to determine if this affected any of the individual sample results. Any affected samples must be reanalyzed, if possible. If the second run of analysis shows acceptable recoveries, the reason for the initial poor recoveries must be determined, eliminated and documented. The analysis with the acceptable result is to be reported.

ii) Sample results with out of control surrogates must be qualified when reporting to the customer as showing adverse matrix effects.

Teklab monitors tabulations and quality control charts of the results from all quality control indicators via the LIMS

A) For each approved test method, or combination of similar test methods; and
B) For each matrix.

Tabulations, quality control charts or any combination of tabulations and quality control charts of results of quality control indicators include or are linked electronically to the following information:

A) Title;
B) Identification of standard operating procedures (SOP) which requires collection of quality control procedure data;
C) Name of quality control procedure being tabulated;
D) Analytical method;
E) Analyte;
F) Analyte units of measure;
G) Matrix;
H) Fortification concentration;
I) Mean;
J) Standard deviation;
K) Upper control limit (UCL);
L) Lower control limit (LCL);
M) Upper warning limit (UWL);
N) Lower warning limit (LWL);
O) Date of analysis;
P) Sample/QC Sample ID;
Q) Analyst's identification;

References for Minimum QC Requirements:

The individual and overall level of QC effort will be, at a minimum, equivalent to the level of QC effort specified under the NELAP certification program. The level of QC effort for samples not

covered by NELAP certification will be, at a minimum, the QC required by the specified test method ("SW-846, Standard Methods for the Examination of Water, Wastewater", or "Methods for Chemical Analysis of Water and Wastewater" EPA 600). The level of QC effort for testing TCLP organic (Volatile, Semi-Volatile and Pesticide/Herbicide and PCB) will conform to Protocols of SW-846.

Accuracy, Precision and Sensitivity of Analysis

The fundamental QA/QC objective with respect to accuracy, precision and sensitivity of laboratory analytical data is to achieve the QC acceptance criteria of the analytical protocols. The accuracy, precision and sensitivity of all parameters are listed or referenced in the individual SOPs

26.4 Proficiency Test Samples or Interlaboratory Comparisons

Laboratory performance is monitored internally through the review of worksheets or batches, examination of analyst techniques, internal blind QC samples and participation in performance evaluation studies. Examples of this are performance studies from approved TNI PT providers, such as WP, WS, AE and RCRA studies and client provided blind Quality Control studies. These studies are intended to evaluate laboratory performance and help identify problems that exist.

26.4.1 Compliance to Accreditation Requirements

The laboratory must successfully analyze at least two TNI-compliant PT samples per calendar year for each accreditation Fields of Proficiency Testing (FoPT) for which the laboratory is accredited. An exception is made for analytes where there is no PT available from any PTPA approved PT provider at least twice per year. In these cases the lab will run the PTs in the minimum time frame the PTs are available and not at all if they are not available.

The successive PTs are analyzed at least five months apart and no more than 7 months apart unless the PT is being used for corrective action to reinstate accreditation or when applying for initial accreditation, in which case the dates of successive PT samples for the same accreditation FoPT is at least fifteen days apart.

To obtain and/or maintain TNI accreditation Teklab must also:

a. Successfully complete two PT studies for each requested PT field of testing within the most recent three rounds attempted.
b. Have the most recent three rounds attempted occurring within 18 months of the laboratory's application date.
c. Continue to complete PT studies for each PT field of testing and maintain a history or at least two acceptable PT studies for each field of testing out the most recent three.
d. Obtain PT samples from an TNI PTOB/PTPA approved PT Provider.
e. Authorize the PT provider to release all accreditation and remediation results and acceptable/not acceptable status directly to their NELAP primary accrediting authority in addition to Teklab.
f. Ensure that all PT samples are handled in the same manner as real environmental samples utilizing the same staff, methods, procedures, equipment, facilities and

frequency of analysis, as normally used for routine analysis of that analyte and matrix type.

g. Ensure that corrective actions are taken for any failed studies, including determining root cause of the failure. Ensure that documentation of the any corrective actions is provided to the primary accrediting authority.
h. Make available to the assessors of the Primary Accrediting Authority, during on-site audits of Teklab, all laboratory records related to the PT samples and their reporting.

26.4.2 PT Sample Handling and Analysis

Proficiency Testing (PT) samples are treated as typical samples in the normal production process where possible, including the same analysts, preparation, calibration, quality control and acceptance criteria, sequence of analytical steps, number of replicates, and sample log-in. PT samples are not analyzed multiple times unless routine environmental samples are analyzed multiple times. Where PT samples present special problems in the analysis process, they will be treated as laboratory samples where clients have special requests.

The type, composition, concentration and frequency of quality control samples analyzed with the PT samples are the same as with typical samples.

Prior to the closing date of a study, Teklab personnel must not:

- Subcontract analysis of a PT sample to another laboratory being run for accreditation purposes.
- Knowingly receive and analyze a PT for another laboratory being run for accreditation purposes.
- Communicate with an individual from another laboratory concerning the analysis of the PT sample.
- Attempt to find out the assigned value of a PT from the PT Provider.

26.4.3 PT Reporting Procedure (TNI 2009 V1M2 Section 5.2)

Teklab shall evaluate and report the analytical result for accreditation Fields of Proficiency Testing (FoPT) as follows:

a) For instrument technology that employs a multi-point calibration, the laboratory shall evaluate the analytical result to the value of the lowest calibration standard established for the test method used to analyze the PT sample. The working range of the calibration under which the PT sample is analyzed shall be the same range as used for routine environmental samples.
   i. A result for any FoPT at a concentration above or equal to the lowest calibration standard shall be reported as the resultant value.
   ii. A result for any FoPT at a concentration less than the lowest calibration standard shall be reported as less than the value of the lowest calibration standard.
b) For instrument technology (such as ICP-AES or ICP-MS) that employ standardization with a zero point and a single point calibration standard, the laboratory shall evaluate the analytical result to PQL established for the test method

used to analyze the PT sample. The PQL for the FoPT shall be the same as used for routine environmental samples.

i. A result for any FoPT at a concentration above or equal to the PQL shall be reported as the resultant value.
ii. A result for any FoPT at a concentration less than the PQL shall be reported as less than the value of the PQL.

The laboratory shall report the analytical results for accreditation and experimental FoPTs to the Proficiency Testing Provider (PTP) on or before the closing date of the study using the reporting format specified by the PTP.

On or before the closing date of the study, the laboratory shall authorize the PTP to release the laboratory's final evaluation report directly to the laboratory's Primary Accreditation Body (AB)

Teklab must ensure that corrective actions are taken for any failed studies, including determining root cause of the failure. It must also ensure that documentation of the any corrective actions is provided to the primary accrediting authority. The laboratory institutes corrective action procedures for failed PT samples following the guidelines in Section 13 – "Corrective Action".

The laboratory must maintain a copy of the online data entry summary when the PT results are submitted online. These data summary documents are stored on the server in the applicable Proficiency Testing folder. Electronic copies of PT data and documentation are stored on the server or storage hardware indefinitely.

When requested, the laboratory shall submit 'analytical data packages' to the accrediting authority for analytes/methods that are not readily available on Performance testing studies.

Teklab must make available to the assessors of the Primary Accrediting Authority, during on-site audits of Teklab, all laboratory records related to the PT samples and their reporting.

26.5 Data Review

The laboratory reviews all data generated in the laboratory for compliance with SOP, laboratory and, where appropriate, client requirements. See SOP1290 for information on data review.

26.6 Water Quality

Three water sources are in use at the Teklab, Inc. Collinsville facility: general deionized water, volatiles lab deionized water, and metals lab deionized water.

a. General laboratory deionized water produced by running tap water through an activated carbon filter (tank 1) followed by a cation exchange resin bed filter (tank 2) followed by an anion exchanged resin bed filter (tank 3) followed by two mixed bed resin filter (tank 4 and

5). Tank 5 serves as a backup tank. Tank 4 and 5 are monitored to ensure the resistivity is greater than 1 megohm-cm. An audible alarm will sound if resistivity is less than 1 megohm-cm.

b Volatiles lab deionized water uses general laboratory deionized water as the feed water then passes it through one more activated carbon filter, to remove all trace amounts of organics, then passes through a 0.45µm filter to trap any carbon residue that may leave the carbon filter. This water has a minimum quality of medium water quality.

c. Metals lab deionized water uses general laboratory water as the feed water then passes through a Thermo brand "high capacity" 2 bed resin filter followed by 2 Thermo brand " Ultrapure DI" filters with mixed resin beds. This water passes through an in-line resistivity meter, where all readings are greater than 15 megohm-cm with typical readings of 18megohm-cm. This water meets high quality water specifications.

Section 27 – Reporting the Results

(TNI V1:M2 – Section 5.10)

The result of each test performed is reported accurately, clearly, unambiguously, and objectively and complies with all specific instructions contained in the test method. Laboratory results are reported in a test report that includes all the information requested by the client and necessary for the interpretation of the test results and all information required by the method used. See SOP#1290 for more information on reporting of results.

The laboratory pays particular care and attention to the arrangement of the report, especially with regard to presentation of the sample results and ease of assimilation by the reader. The format is carefully and specifically designed for each type of approved test method carried out, but the headings are standardized as far as possible.

27.1 Test Reports

The laboratory issues sample data or sample result reports accurately and in a manner that is understandable to the recipient. Each test report generated contains the following information (unless the laboratory has a valid reason for not doing so, such as a written agreement with the client).

- Name, address and phone number of the laboratory;
- Name and address of client and project;
- The TNI logo with the phrase "NELAP accredited Laboratory". The laboratory's accreditation number appears on the case narrative page of each report;
- Unique identification of the report (such as work order number) and of each page and identification of the total number of pages. Each page in each section is identified as a number of the total report pages, for example 3 of 10 or 1 of 20.
- Report title, such as "Laboratory Results";

- Description and identification of samples (including client ID code);
- Date of sample receipt, sample collection and sample analysis (time of sample collection, if provided by client, and time of sample preparation (if requested by the client) and analysis, if the required holding time for either activity is less than or equal to 48 hours);
- Approved test method and preparation method utilized, including revision numbers;
- Clear indication of TNI accredited analysis by listing the letters "NELAP" next to each accredited analyte. Analytes that are not NELAP accredited are designated by an asterisk in the certification column. An explanation of the asterisk is also noted in the Definitions section of the final report;
- Sample results with any failures or deviations from approved test methods or QC criteria identified in the case narrative, sample narrative, and/or with data qualifiers;
- Signature and name or electronic signature and name, and title of the individuals accepting responsibility for the content of the report and date of issue;
- Clear identification, including the lab name or accreditation number of any sample results that were generated by a subcontracted laboratory;
- A description of the calculations or operations performed on the data, a summary and analysis of the data, and a statement of conclusions drawn from the analysis;
- Identification of the reporting units, such as µg/L or mg/kg;
- A statement that the report shall not be reproduced, except in full, without the written approval of the laboratory, where appropriate;
- Where applicable, a statement to the effect that the sample results relate only to the analytes of interest tested or to the sample as received by the laboratory;
- Where applicable, characterization and condition of the sample;
- Where applicable, reference to sampling procedure; and
- Clear, unequivocal identification of analytical results generated by an approved test method, for which the laboratory is accredited in accordance with the laboratory's accreditation.

27.2 Supplemental Test Report Information

When necessary for interpretation of the results or when requested by the client, test reports include the following additional information:

a) deviations from, additions to, or exclusions from the test method, information on specific test conditions, such as environmental conditions, and any non-standard conditions that may have affected the quality of the results, and any information on the use and definitions of data qualifiers;

b) a statement of compliance/non-compliance when requirements of the management system are not met, including identification of test results that did not meet the laboratory and regulatory sample acceptance requirements, such as holding time, preservation, etc.;

c) where applicable and when requested by the client, a statement on the estimated uncertainty of the measurement is available

d) Teklab does not include opinions and interpretations in laboratory reports

e) additional information which may be required by specific methods or client;

f) qualification of results with values outside the calibration range as appropriate.

27.3 Environmental Testing Obtained from Subcontractors

When Teklab must subcontract analysis due to workload, need for further expertise, temporary incapacity, or on a continuing basis, work is placed with a laboratory accredited under NELAP for the test to be performed or with a laboratory that meets the applicable statutory and regulatory requirements for performing the tests and submitting the results of test performed.

All subcontracted analyses and the name of the subcontracted lab are documented in the case narrative of the final report. Any non-NELAP accredited work is designated by an asterisk in the certification column.

The intent to subcontract analysis is specified in the project quote when Teklab intends to subcontract any part of a project. When possible, Teklab will advise the client in writing of any subcontracted analysis.

Teklab maintains a register of all subcontractors that it uses for environmental tests and a record of the evidence of compliance for each. The subcontractors may report their results in writing or electronically. A copy of the subcontractors report is made available to the client if requested. A record of subcontracted analysis is retained at Teklab and is archived in accordance with this manual. See Section 10 for more information on Subcontracting.

27.4 Electronic Transmission of Results

The laboratory ensures that when clients require transmission of test results by telephone, tele-facsimile or other electronic or electromagnetic means, laboratory personnel follow documented procedures that ensure the requirements of the TNI Standard and associated procedures to protect the confidentiality and proprietary rights of the client are met (see Section 21- “Environmental Methods and Method Validation”). All electronic transmissions are limited to the contracting client and their designated recipients. Any transmission to a third party requires written confirmation by the contracting client.

27.4.1 Electronic Data Deliverables (EDDs)

EDDs are client driven deliverables that can be produced in various file formats; such as text and Excel files. EDDs, when requested by a client, are provided in addition to the final report. EDDs are prepared using Microsoft Access/VBA, which exports the EDD into the file type the client has requested. EDD files are prepared by Project Managers for the client. Teklab's IT Programmer develops the EDD per client request.

Some clients EDDs are developed to use Equis Data Processor (EDP) software to check the EDD file using the client provided format and reference files. The EDP software checks for, amongst other things, formatting errors and valid values. Problematic EDDs are rejected and flagged for specific errors, helping facilitate any corrections before the EDD is sent to the customer. All electronic transmissions follow Section 27.4 above.

27.5 Amendments to Test Reports

Material amendments to a test report after it has been issued are made only in the form of another document or data transfer. All supplemental reports meet all the requirements for the initial report and the requirements of this Quality Manual.

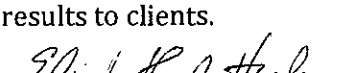
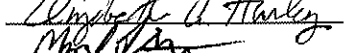
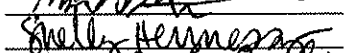
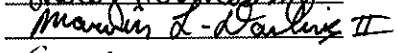
See SOP1290 for more information on revised reports.

27.6 Electronic signatures

Electronic signatures used in LIMS reports are stored securely in the LIMS SQL tables. Electronic signatures used for purposes out with the LIMS (e.g. signing SOPs, Teklab correspondence) should be stored on the users U Drive.

27.7 Report Signatories

Below is a list of parties authorized to release testing results to clients.

Elizabeth Hurley	Director of Customer Service	
Michael Austin	Project Manager	
Shelly Hennessy	Project Manager	
Marvin Darling	Project Manager	
Emily Pohlman	Project Manager	

Section 28 - Safety

Safety is the number one priority of every employee at Teklab, Inc. Teklab trains employees to ensure that no work is performed in an unsafe environment. Where safety practices are included as part of an approved test method, these practices are strictly followed. While more specific safety criteria are not an aspect of this manual, laboratory personnel must always apply appropriate safety practices.

The specifics of the Teklab safety program are detailed in the Teklab Chemical Hygiene Plan and are defined by the Teklab Safety Officer at monthly safety meetings. Teklab complies with and exceeds all applicable OSHA regulations concerning safe laboratory and workplace operations. See SOP 1161 for more information on Safety.

Teklab's Emergency Action Plan (EAP) is reviewed at least annually by the Safety Officer.

Fire/spill drills are conducted annually.

Section 29 - Bibliography

References:

1. The TNI Standard: Modules 1-7 in the 2009 TNI Environmental Laboratory Sector Standard – Volume 1 – Management and Technical Requirements for Laboratories Performing Environmental Analysis (EL-V1, M1 through M7, ISO-2009).

2. "Test Method For The Evaluation of Solid Wastes SW846", "Laboratory Manual Physical/Chemical Properties", volumes 1A, 1B, and 1C, 3rd edition, Office of Solid Waste and Emergency Response, Environmental Protection Agency.

3. "Standard Method for the Examination of Water and Wastewater" online

4. EPA No. 600/4-79-020, "Methods of Chemical Analysis of Water and Wastes" (March 1983).

5. "Quality Assurance of Chemical Measurements" 1989, John Keenan Taylor, Lewis Publishers, Inc.

6. 40 CFR Part 136, Appendix B

Appendix F - Instrumentation and Software list

Instrumentation and Software

The following section contains information on the type and number of instrumentation, and computer systems/software packages at Teklab, Inc.

INSTRUMENTATION

Teklab Air Laboratory:

- Instrument U-Agilent 7890A (GC)/5975C Inert XL(MS) with Entech 7500A Robotic Auto sampler, Entech 7100AR Sample Preconcentrator and Micro Computer-1 each
- Entech 4600A Dynamic Diluter and Micro Computer* -1 each
- Entech 3100A Canister Cleaner system with Thermo Scientific Oven and Micro Computer*- 1 each *the Micro Computer is shared by the two systems
- Labconco 3955200 Fume Absorber
- Mettler AE160 Analytical Balance

Corporate:

Volatile Organic Section

- Instrument A - Hewlett-Packard 5890 Series II GC / 5971 Mass Spectrometer (upgraded to 5972) with a metal quad upgrade, 60 meter Restek Rtx-624 column with 0.25mm ID, using a split/splitless injection port and glass injection port liner. No cryogenic system is used. 1 each
  - Tekmar LSC3000 sample concentrator.
  - Varian Archon autosampler.
- Instrument F - Hewlett-Packard 5890 Series II GC / 5972 Mass Spectrometer, 60 meter Restek Rtx-624 column with 0.25mm ID, using a split/splitless injection port and glass injection port liner. No cryogenic system is used.
  - Tekmar LSC3000 sample concentrator
  - Varian Archon autosampler.
- Instrument N - Hewlett-Packard 5890 Series II Plus GC / 5972 Mass Spectrometer with a metal quad upgrade, 30 meter Restek Rxi-624SilMS column with 0.25mmID, using a split/splitless injection port and glass injection port liner. No cryogenic system is used. 1 each
  - Tekmar LSC3000 sample concentrator.
  - Varian Archon autosampler.
- Instrument R - Hewlett-Packard 6890 Series GC / 5973 Mass Spectrometer, 30 meter Restek Rxi - 624SilMS column with 0.25mm ID, using a split/splitless injection port and glass injection port liner. No cryogenic system is used.
  - Tekmar LSC3000 sample concentrator
  - Varian Archon autosampler.
- Instrument T - Hewlett-Packard 6890 Series GC / 5973 Mass Spectrometer, 30 meter Restek Rxi - 624SilMS column with 0.25mm ID, using a split/splitless injection port and glass injection port liner. No cryogenic system is used.
  - Tekmar LSC3100 sample concentrator.
  - Varian Archon autosampler

- Instrument Y - Hewlett-Packard 5890 Series II GC/5972 MS, 30 meter Restek Rxi-624SilMS column with 0.25mmID, using a split/splitless injection port and glass injection port liner. No cryogenic system is used. 1 each
  - Tekmar LSC3000 sample concentrator.
  - Varian Archon autosampler.
- Mitsubishi brand AOX-200 analyzer "TOX-3" – 1 each

Organic Section
- Instrument AA - 6890 Series II GC - 5973N MS with 6890 Series Injector, with computer
- Instrument AB - 6890 Series II GC - 5973N MS with 6890 Series Injector, with computer
- Instrument B - 5890 Series II GC - 5971 MS with 7673 Series Injector, with computer
- Instrument D - 5890 Series II GC - FID with 7673A Series Injector, with computer
- Instrument E - 5890 Series II GC - Dual ECD with 7673A Series Injector, with computer
- Instrument H - 5890 Series II GC - Dual ECD with 7673 Series Injector, with computer
- Instrument I - 5890 Series II GC - FID with 7673 Series Injector, with computer
- Instrument L - 5890 Series II GC - FID with computer
- Instrument M - 5890 Series II GC - 5972 Mass Spec with 7673 Series Injector, with computer
- Instrument P - 5890 Series II GC - 5971A Mass Spec with 7673 Series Injector, with computer
- Instrument Q - 5890 Series II GC - Dual ECD with 7673 Series Injector, with computer
- Instrument S - HP – 6890 GC - 5973 MS with 6890 Series Injector, with computer
- Instrument X - 5890 Series II GC - Dual Electron Capture Detectors, with computer
- Instrument Z - HP 6890 Series II GC - 5973 MS Model 6890/5973, with computer

Organic Prep Lab
- Fisher Scientific, 550 Sonic Dismembrator and VirSonic Cell Disrupter - 6 each
- Zymark, Turbovap LV evaporator – 2 each
- Glas-Col, 3D Floor Shaker – 2 each
- VWR, Refrigerated Recirculator
- Milestone ETHOS EX microwave extraction system
- NESLAB Refrigerated/Recirculator

Metals Section
- Teledyne Leeman Labs CVAA Hydra II AA Automated Hg Analyzer
- Teledyne Leeman Labs Hydra AF Gold Plus Mercury Analyzer (CVAFS), Autosampler and Micro computer
- Varian MPX CCD Simultaneous ICP-OES – 1 each
- Agilent Technologies CCD Simultaneous ICP-OES - 1 each
- Thermo Fisher Scientific iCAP Qc ICP-MS - 2 each

Metals Prep
- Hot Block Digester, 54 Position with ETR-3200 Controller - 4 each

Inorganic Section
- Environmental Express Ammonia/OOH Micro Distillation Unit - 1 each
- Environmental Express Simple Cyanide Distillation Unit – 3 each
- Parr, Oxygen Bomb Calorimeter, with Parr Bomb Ignition Unit (2 Bomb Units) - 1 each
- Thermo Orion 720A – 1 each

- VWR Symphony B10P - 1 each
- Thermo pH Meter, Orion 3 Star
- Hach DR/2000 Direct Reading Spectrophotometer - 1 each
- Hach DR/2400 Direct Reading Spectrophotometer - 1 each
- Hach DR/2800 Direct Reading Spectrophotometer - 1 each
- Hach DRB 200 25 Position Reactor - 1 each
- Hach 25 Position Reactor – 2 each
- Environmental Express; Hexane Extraction Method/Solid Phase Extraction Manifold - 21 each
- Buchi Rotavapor R-114, waterbath B480 - 1 each
- Buchi Rotovapor R-210, waterbath B491 – 1 each
- Hach 2100 P Turbidimeter - 1 each
- YSI Model 59 Dissolved Oxygen Meter, with 5905 Probe - 1 each
- YSI Model 5000 Dissolved Oxygen Meter, with 5905 Probe - 1 each
- Skalar San++ System, with 4 autoanalyzers, 1 DOC IR detector, 4 Spectrophotmetric Detectors, 1 Amperimetric Detector, and 4 Autosamplers.
- Branson 1510 Ultrasonic Cleaner
- A.I. Scientific Digestion AIM 500-C, 50 Position Digestor
- Koehler Instrument CO. Flash Point Tester – 1 each
- Small scale Flash Point Tester
- Thermoline Type 6000 Muffle Furnace -1 each
- Equatherm Environmental Incubator -1 each
- Precision Low Temperature Incubator -1 each
- Precision Low Temperature Incubator 815 – 1 each
- Fisher Scientific Low Temperature Incubator – 1 each
- Fisher Scientific, Digital Conductivity Meter Model Accumet 30 - 1 each
- Analytical Balances capable of reading 0.1mg – 2 each
- Analytical Top Loader Balance capable of reading 0.01g – 3 each

General Lab Use
- Analytical Balances capable of reading 0.1 mg - 2 each
- Analytical Top Loader Balances capable of reading .01 g - 6 each
- Dynac II Centrifuge - 1 each

Field Use
- Orion pH/temperature meter – 1 each
- Oakton pH/ pH/conductivity/temperature meters – 4 each
- Hach Turbidity Meter Pocket Turbidimeter Cat# 52600-00 – 1 each

COMPUTER SYSTEMS & SOFTWARE PACKAGES

Teklab, Inc. software listing:

- Microsoft Server 2003 (Standard and Enterprise)

- Microsoft SQL Server 2005

- Microsoft Exchange Server 2007
- Symantec Backup Exec 11d
- Desktop Operating Systems: Windows 98, Windows 2000, Windows NT, Windows XP, Windows Vista, Windows 7 and Windows 8
- Webroot Version9
- Khemia Omega VTEN-64 ELIMS(mod) Environmental Laboratory Information Management System with EDD Module
- Microsoft Office 2003 Professional Edition (Access, Excel, Word, PowerPoint & FrontPage, Outlook) and Microsoft Office 2010 Professional Edition (Excel, Word, PowerPoint & Outlook)
- Adobe Acrobat 7.0, 8.0, 9.0, 10 ActivePDF Composer
- PaperPort 9 Deluxe and PaperPort 12
- Agilent_MSDChemStation E.02.00.493
- Entech Instruments ESP Version 2
- Entech Instruments SmartLab II V4.176
- Quick Books Pro 2014 Accounting Software
- Hewlett-Packard G1032C rev. C.01.00 GC\MS EnviroQuant
- Hewlett-Packard G1701AA rev. C.03.02 GC\MS EnviroQuant
- Hewlett-Packard G1701AA rev. A.03.00 GC\MS EnviroQuant
- Hewlett-Packard G1701BA rev. B.01.00 GC\MS EnviroQuant
- Hewlett-Packard G1701AA rev. C.03.02 GC EnviroQuant
- Hewlett-Packard G1701CA V C.00.00 GC Chemstation
- Hewlett-Packard G1701DA D.02.00 SPI GC/MS
- Thermo Fisher Scientific Qtegra iCAP Q ICP-MS Software
- Varian GC/MS Workstation 6.4.1 with EnviroPro.
- Skalar - FlowAccess Software Version 1.04.7

- 7-Zip
- Win2Pdf
- Gladwin PrintScreen Version 4.4
- Redgate SQL Toolbelt
- UltraEdit
- UltraCompare

Appendix E - Data Qualifiers

#	Unknown hydrocarbon
B	Analyte detected in associated Method Blank
E	Value above quantitation range
H	Holding times exceeded
J	Analyte detected below quantitation limits
M	Manual Integration used to determine area response
N	Parameter not NELAC certified
ND	Not Detected at the Reporting Limit
R	RPD outside accepted recovery limits
S	Spike Recovery outside recovery limits
X	Value exceeds Maximum Contaminant Level
DF	Dilution Factor
RL	Reporting Limit
Surr	Surrogate Standard added by lab
TNTC	Too numerous to count (>200 CFU)
Q	QC criteria failed or noncompliant CCV
NELAP	IL NELAP and NELAP accredited field of testing
IDPH	Illinois Department of Public Health
C	Client requested RL below PQL
D	Diluted out of sample
E	Value above quantitation range
MI	Matrix interference
DNI	Did not ignite

Appendix D

Laboratory Accreditation/Certification List

Teklab Inc maintains the following certifications and accreditations

State	Dept	Cert #	NELAP	Exp Date	Location
Illinois	IEPA	100226	NELAP	1/31/2019	Collinsville
Kansas	KDHE	E-10374	NELAP	4/30/2019	Collinsville
Louisiana	LDEQ	166493	NELAP	6/30/2019	Collinsville
Louisiana	LDEQ	166578	NELAP	6/30/2019	Collinsville Air
Oklahoma	ODEQ	9978	NELAP	8/31/2019	Collinsville
Illinois	IDPH	17584		5/31/2019	Collinsville
Arkansas	ADEQ	88-0966		3/14/2019	Collinsville
Indiana	ISDH	C-IL-06		1/31/2019	Collinsville
Kentucky	UST	0073		1/31/2019	Collinsville
Kentucky	KDEP	98006		12/31/2018	Collinsville
Louisiana	LDPH	LA170027		12/31/2018	Collinsville
Missouri (Micro)	MDNR	00930		5/31/2019	Collinsville
Missouri	MDNR	00930		1/31/2019	Collinsville
Tennessee	TDEC	04905		1/31/2019	Collinsville

The certificates and parameter lists (which may differ) for each organization can be found on the following pages and on the Teklab Inc website.

If accreditation is terminated or suspended, the laboratory will immediately cease to use the certificate number reference in any way and inform clients impacted by the change.

JOHN BEL EDWARDS
GOVERNOR

CHUCK CARR BROWN, PH.D.
SECRETARY

State of Louisiana

DEPARTMENT OF ENVIRONMENTAL QUALITY
ENVIRONMENTAL SERVICES

Read Receipt Requested

AI No. 166578
Activity No. ACC20180001
LELAP Lab ID # 05003
Accreditation Year FY 2019
Renewal due FY 2022

Ms. Claire Bogner
Teklab Air Laboratory
5445 Horseshoe Lake Rd
Collinsville, Illinois 62234

Re: Renewal Scope of Accreditation

Dear Ms. Bogner:

On April 20, 2018, the Louisiana Environmental Laboratory Accreditation Program (LELAP) received a renewal application for Accreditation.

The Louisiana Department of Environmental Quality's laboratory accreditation program, in accordance with Louisiana Administrative Code, Title 33, Part I, Subpart 3, Laboratory Accreditation, accredits this laboratory for Fiscal Year 2019. This accreditation does not constitute an endorsement of the suitability of the listed methods for any specific purpose. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. The laboratory is accredited for the method as identified on the application for accreditation; if the method is partially identified on the application for accreditation, the laboratory is accredited for the versions listed on the current application or referenced in the laboratory standard operating procedure.

National Environmental Laboratory Accreditation Program (NELAP) accreditation is granted only for those methods/analytes for which "NELAP" is indicated as the type of accreditation. "STATE" is indicated as the type of accreditation for those methods/analytes for which accreditation by the Louisiana Environmental Laboratory Accreditation Program (LELAP) is granted. Accreditation is dependent on the laboratory's successful ongoing compliance with regulations as outlined in the Louisiana Administrative Code, Title 33, Part I, Subpart 3, Laboratory Accreditation, and with the standards adopted by the NELAP Accreditation Council.

The accreditation certificate is the property of the State of Louisiana. Should your accreditation be suspended or revoked, your laboratory must return the certificate of accreditation to the department and delete any electronic copies until your accreditation status is restored.

LAC 33:I.5313.A and/or the 2009 TNI Standard require that the laboratory report include all relevant information. Therefore, the certificate number shall be placed in the upper right corner of all laboratory reports. If the test report includes results of any test for which the laboratory is not accredited, the unaccredited results must be clearly identified as such.

We request that you examine the scope of accreditation attachment for accuracy and completeness. If you find that an analyte for which you expected to be accredited is not listed, please examine your records to ensure that:

1. You have met the requirements for successful participation in proficiency test studies as outlined in LAC 33:I.4711 and in the 2009 TNI Standard.

2. In the case of accreditation by recognition, the requested analyte must be listed for the requested method and matrix on both the certificate issued by the Primary Accreditation Body ***and*** on the Louisiana application form.

If after reviewing this information, the scope and/or certificate are inaccurate, please notify us immediately.

If you have any questions, please contact your assigned assessor Dr. Kimberly Hamilton-Wims, Environmental Scientist at (225) 219-3302.

Sincerely,

Cheryl Sonnier Nolan
Administrator
Public Participation and Permit Support Services Division

22 June 2018
Date

CSN:PB:khw

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Is hereby granting a Louisiana Environmental Laboratory Accreditation to

Teklab Air Laboratory
1355 North Bluff Rd Ste F
Collinsville, Illinois 62234

Agency Interest No. 166578
Activity No. ACC20180001

According to the Louisiana Administrative Code, Title 33, Part I, Subpart 3, LABORATORY ACCREDITATION, the State of Louisiana formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part I, Subpart 3 requirements and agrees to adapt to any changes in the requirements. It also acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part I and the 2009 TNI standards by which the laboratory was assessed. Please contact the Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP) to verify the laboratory's scope of accreditation and accreditation status.

Accreditation by the State of Louisiana is not an endorsement or a guarantee of validity of the data generated by the laboratory. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. To be accredited initially and maintain accreditation, the laboratory agrees to participate in two single-blind, single-concentration PT studies, where available, per year for each field of testing for which it seeks accreditation or maintains accreditation as required in LAC 33:I.4711.

Cheryl Sonnier Nolan
Administrator
Public Participation and Permit Support Services Division

Issued Date: 22 June 2018

Effective Date: July 1, 2018
Expiration Date: June 30, 2019
Certificate Number: 05003

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Effective Date: July 1, 2018

Teklab Air Laboratory
AI Number: 166578
Activity No. ACC20180001
Expiration Date: June 30, 2019

1355 North Bluff Rd Ste F, Collinsville, Illinois 62234

Certificate Number: 05003

Air Emissions

Analyte	Method Name	Method Code	Type	AB
5105 - 1,1,1,2-Tetrachloroethane	EPA TO-15	10248803	NELAP	LA
5160 - 1,1,1-Trichloroethane	EPA TO-15	10248803	NELAP	LA
5110 - 1,1,2,2-Tetrachloroethane	EPA TO-15	10248803	NELAP	LA
5195 - 1,1,2-Trichloro-1,2,2-trifluoroethane	EPA TO-15	10248803	NELAP	LA
5165 - 1,1,2-Trichloroethane	EPA TO-15	10248803	NELAP	LA
4630 - 1,1-Dichloroethane	EPA TO-15	10248803	NELAP	LA
4640 - 1,1-Dichloroethylene	EPA TO-15	10248803	NELAP	LA
5155 - 1,2,4-Trichlorobenzene	EPA TO-15	10248803	NELAP	LA
5210 - 1,2,4-Trimethylbenzene	EPA TO-15	10248803	NELAP	LA
4585 - 1,2-Dibromoethane (EDB, Ethylene dibromide)	EPA TO-15	10248803	NELAP	LA
4695 - 1,2-Dichloro-1,1,2,2-tetrafluoroethane (Freon-114)	EPA TO-15	10248803	NELAP	LA
4610 - 1,2-Dichlorobenzene	EPA TO-15	10248803	NELAP	LA
4635 - 1,2-Dichloroethane (Ethylene dichloride)	EPA TO-15	10248803	NELAP	LA
4655 - 1,2-Dichloropropane	EPA TO-15	10248803	NELAP	LA
5215 - 1,3,5-Trimethylbenzene	EPA TO-15	10248803	NELAP	LA
9318 - 1,3-Butadiene	EPA TO-15	10248803	NELAP	LA
4615 - 1,3-Dichlorobenzene	EPA TO-15	10248803	NELAP	LA
4620 - 1,4-Dichlorobenzene	EPA TO-15	10248803	NELAP	LA
4735 - 1,4-Dioxane (1,4- Diethyleneoxide)	EPA TO-15	10248803	NELAP	LA
100100 - 1-Methyl-2-isopropylbenzene (o-Cymene)	EPA TO-15	10248803	NELAP	LA
5220 - 2,2,4-Trimethylpentane (Isooctane)	EPA TO-15	10248803	NELAP	LA
4410 - 2-Butanone (Methyl ethyl ketone, MEK)	EPA TO-15	10248803	NELAP	LA
4535 - 2-Chlorotoluene	EPA TO-15	10248803	NELAP	LA
4860 - 2-Hexanone	EPA TO-15	10248803	NELAP	LA
4542 - 4-Ethyltoluene	EPA TO-15	10248803	NELAP	LA
4995 - 4-Methyl-2-pentanone (MIBK)	EPA TO-15	10248803	NELAP	LA
4315 - Acetone	EPA TO-15	10248803	NELAP	LA
4320 - Acetonitrile	EPA TO-15	10248803	NELAP	LA
4325 - Acrolein (Propenal)	EPA TO-15	10248803	NELAP	LA
4340 - Acrylonitrile	EPA TO-15	10248803	NELAP	LA
4355 - Allyl chloride (3-Chloropropene)	EPA TO-15	10248803	NELAP	LA
4375 - Benzene	EPA TO-15	10248803	NELAP	LA
5635 - Benzyl chloride	EPA TO-15	10248803	NELAP	LA
4395 - Bromodichloromethane	EPA TO-15	10248803	NELAP	LA
4400 - Bromoform	EPA TO-15	10248803	NELAP	LA
4450 - Carbon disulfide	EPA TO-15	10248803	NELAP	LA
4455 - Carbon tetrachloride	EPA TO-15	10248803	NELAP	LA
4475 - Chlorobenzene	EPA TO-15	10248803	NELAP	LA
4575 - Chlorodibromomethane	EPA TO-15	10248803	NELAP	LA
4485 - Chloroethane (Ethyl chloride)	EPA TO-15	10248803	NELAP	LA
4505 - Chloroform	EPA TO-15	10248803	NELAP	LA
4525 - Chloroprene (2-Chloro-1,3-butadiene)	EPA TO-15	10248803	NELAP	LA
4555 - Cyclohexane	EPA TO-15	10248803	NELAP	LA

Clients and Customers are urged to verify the laboratory's current certification status with the Louisiana Environmental Laboratory Accreditation Program.

Air Emissions

Analyte	Method Name	Method Code	Type	AB
9375 - Di-isopropylether (DIPE) (Isopropyl ether)	EPA TO-15	10248803	NELAP	LA
4625 - Dichlorodifluoromethane (Freon-12)	EPA TO-15	10248803	NELAP	LA
4750 - Ethanol	EPA TO-15	10248803	NELAP	LA
4755 - Ethyl acetate	EPA TO-15	10248803	NELAP	LA
4770 - Ethyl-t-butyl ether (ETBE) (2-Ethoxy-2-methylpropane)	EPA TO-15	10248803	NELAP	LA
4765 - Ethylbenzene	EPA TO-15	10248803	NELAP	LA
4835 - Hexachlorobutadiene	EPA TO-15	10248803	NELAP	LA
4895 - Isopropyl alcohol (2-Propanol, Isopropanol)	EPA TO-15	10248803	NELAP	LA
4900 - Isopropylbenzene	EPA TO-15	10248803	NELAP	LA
4950 - Methyl bromide (Bromomethane)	EPA TO-15	10248803	NELAP	LA
4960 - Methyl chloride (Chloromethane)	EPA TO-15	10248803	NELAP	LA
4990 - Methyl methacrylate	EPA TO-15	10248803	NELAP	LA
5000 - Methyl tert-butyl ether (MTBE)	EPA TO-15	10248803	NELAP	LA
4975 - Methylene chloride (Dichloromethane)	EPA TO-15	10248803	NELAP	LA
5005 - Naphthalene	EPA TO-15	10248803	NELAP	LA
4836 - Propylene	EPA TO-15	10248803	NELAP	LA
5100 - Styrene	EPA TO-15	10248803	NELAP	LA
4370 - T-amylmethylether (TAME)	EPA TO-15	10248803	NELAP	LA
5115 - Tetrachloroethylene (Perchloroethylene)	EPA TO-15	10248803	NELAP	LA
5120 - Tetrahydrofuran (THF)	EPA TO-15	10248803	NELAP	LA
5140 - Toluene	EPA TO-15	10248803	NELAP	LA
5170 - Trichloroethene (Trichloroethylene)	EPA TO-15	10248803	NELAP	LA
5175 - Trichlorofluoromethane (Fluorotrichloromethane, Freon 11)	EPA TO-15	10248803	NELAP	LA
5225 - Vinyl acetate	EPA TO-15	10248803	NELAP	LA
5230 - Vinyl bromide (Bromoethane)	EPA TO-15	10248803	NELAP	LA
5235 - Vinyl chloride	EPA TO-15	10248803	NELAP	LA
5260 - Xylene (total)	EPA TO-15	10248803	NELAP	LA
4645 - cis-1,2-Dichloroethylene	EPA TO-15	10248803	NELAP	LA
4680 - cis-1,3-Dichloropropene	EPA TO-15	10248803	NELAP	LA
5240 - m+p-xylene	EPA TO-15	10248803	NELAP	LA
4435 - n-Butylbenzene	EPA TO-15	10248803	NELAP	LA
4825 - n-Heptane	EPA TO-15	10248803	NELAP	LA
4855 - n-Hexane	EPA TO-15	10248803	NELAP	LA
5090 - n-Propylbenzene	EPA TO-15	10248803	NELAP	LA
5250 - o-Xylene	EPA TO-15	10248803	NELAP	LA
4440 - sec-Butylbenzene	EPA TO-15	10248803	NELAP	LA
4420 - tert-Butyl alcohol	EPA TO-15	10248803	NELAP	LA
4445 - tert-Butylbenzene	EPA TO-15	10248803	NELAP	LA
4700 - trans-1,2-Dichloroethylene	EPA TO-15	10248803	NELAP	LA
4685 - trans-1,3-Dichloropropylene	EPA TO-15	10248803	NELAP	LA

Non Potable Water

Analyte	Method Name	Method Code	Type	AB
NONE	NONE	NONE	NONE	NONE

Solid Chemical Materials

Analyte	Method Name	Method Code	Type	AB
NONE	NONE	NONE	NONE	NONE

Biological Tissue

Analyte	Method Name	Method Code	Type	AB
NONE	NONE	NONE	NONE	NONE

JOHN BEL EDWARDS
GOVERNOR

CHUCK CARR BROWN, PH.D.
SECRETARY

State of Louisiana

DEPARTMENT OF ENVIRONMENTAL QUALITY
ENVIRONMENTAL SERVICES

Read Receipt Requested

AI No. 166493
Activity No. ACC20180001
LELAP Lab ID # 05002
Accreditation Year FY 2019
Renewal due FY 2022

Ms. Claire Bogner
Teklab Inc
5445 Horseshoe Lake Rd
Collinsville, Illinois 62234-7425

Re: Renewal Scope of Accreditation

Dear Ms. Bogner:

On April 20, 2018, the Louisiana Environmental Laboratory Accreditation Program (LELAP) received a renewal application for Accreditation.

The Louisiana Department of Environmental Quality's laboratory accreditation program, in accordance with Louisiana Administrative Code, Title 33, Part I, Subpart 3, Laboratory Accreditation, accredits this laboratory for Fiscal Year 2019. This accreditation does not constitute an endorsement of the suitability of the listed methods for any specific purpose. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. The laboratory is accredited for the method as identified on the application for accreditation; if the method is partially identified on the application for accreditation, the laboratory is accredited for the versions listed on the current application or referenced in the laboratory standard operating procedure.

National Environmental Laboratory Accreditation Program (NELAP) accreditation is granted only for those methods/analytes for which "NELAP" is indicated as the type of accreditation. "STATE" is indicated as the type of accreditation for those methods/analytes for which accreditation by the Louisiana Environmental Laboratory Accreditation Program (LELAP) is granted. Accreditation is dependent on the laboratory's successful ongoing compliance with regulations as outlined in the Louisiana Administrative Code, Title 33, Part I, Subpart 3, Laboratory Accreditation, and with the standards adopted by the NELAP Accreditation Council.

The accreditation certificate is the property of the State of Louisiana. Should your accreditation be suspended or revoked, your laboratory must return the certificate of accreditation to the department and delete any electronic copies until your accreditation status is restored.

LAC 33:I.5313.A and/or the 2009 TNI Standard require that the laboratory report include all relevant information. Therefore, the certificate number shall be placed in the upper right corner of all laboratory reports. If the test report includes results of any test for which the laboratory is not accredited, the unaccredited results must be clearly identified as such.

We request that you examine the scope of accreditation attachment for accuracy and completeness. If you find that an analyte for which you expected to be accredited is not listed, please examine your records to ensure that:

1. You have met the requirements for successful participation in proficiency test studies as outlined in LAC 33:I.4711 and in the 2009 TNI Standard.

2. In the case of accreditation by recognition, the requested analyte must be listed for the requested method and matrix on both the certificate issued by the Primary Accreditation Body ***and*** on the Louisiana application form.

If after reviewing this information, the scope and/or certificate are inaccurate, please notify us immediately.

If you have any questions, please contact your assigned assessor Dr. Kimberly Hamilton-Wims, Environmental Scientist at (225) 219-3302.

Sincerely,

Cheryl Sonnier Nolan
Administrator
Public Participation and Permit Support Services Division

22 June 2018
Date

CSN:PB:khw

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Is hereby granting a Louisiana Environmental Laboratory Accreditation to

Teklab Inc
5445 Horseshoe Lake Rd
Collinsville, Illinois 62234-7425

Agency Interest No. 166493
Activity No. ACC20180001

According to the Louisiana Administrative Code, Title 33, Part I, Subpart 3, LABORATORY ACCREDITATION, the State of Louisiana formally recognizes that this laboratory is technically competent to perform the environmental analyses listed on the scope of accreditation detailed in the attachment.

The laboratory agrees to perform all analyses listed on this scope of accreditation according to the Part I, Subpart 3 requirements and agrees to adapt to any changes in the requirements. It also acknowledges that continued accreditation is dependent on successful ongoing compliance with the applicable requirements of Part I and the 2009 TNI standards by which the laboratory was assessed. Please contact the Department of Environmental Quality, Louisiana Environmental Laboratory Accreditation Program (LELAP) to verify the laboratory's scope of accreditation and accreditation status.

Accreditation by the State of Louisiana is not an endorsement or a guarantee of validity of the data generated by the laboratory. Accreditation of the environmental laboratory does not imply that a product, process, system, or person is approved by LELAP. To be accredited initially and maintain accreditation, the laboratory agrees to participate in two single-blind, single-concentration PT studies, where available, per year for each field of testing for which it seeks accreditation or maintains accreditation as required in LAC 33:I.4711.

Cheryl Sonnier Nolan
Administrator
Public Participation and Permit Support Services Division

Issued Date: 22 June 2018

Effective Date: July 1, 2018
Expiration Date: June 30, 2019
Certificate Number: 05002

STATE OF LOUISIANA
DEPARTMENT OF ENVIRONMENTAL QUALITY

Effective Date: July 1, 2018

Teklab Inc
AI Number: 166493
Activity No. ACC20180001
Expiration Date: June 30, 2019

5445 Horseshoe Lake Rd, Collinsville, Illinois 62234-7425

Certificate Number: 05002

Air Emissions

Analyte	Method Name	Method Code	Type	AB
6380 - 1-Methylnaphthalene	EPA TO-13A	10248405	NELAP	LA
5795 - 2-Chloronaphthalene	EPA TO-13A	10248405	NELAP	LA
6385 - 2-Methylnaphthalene	EPA TO-13A	10248405	NELAP	LA
5500 - Acenaphthene	EPA TO-13A	10248405	NELAP	LA
5505 - Acenaphthylene	EPA TO-13A	10248405	NELAP	LA
5555 - Anthracene	EPA TO-13A	10248405	NELAP	LA
5575 - Benz(a)anthracene	EPA TO-13A	10248405	NELAP	LA
5580 - Benzo(a)pyrene	EPA TO-13A	10248405	NELAP	LA
5585 - Benzo(b)fluoranthene	EPA TO-13A	10248405	NELAP	LA
5605 - Benzo(e)pyrene	EPA TO-13A	10248405	NELAP	LA
5590 - Benzo(g,h,i)perylene	EPA TO-13A	10248405	NELAP	LA
5600 - Benzo(k)fluoranthene	EPA TO-13A	10248405	NELAP	LA
5855 - Chrysene	EPA TO-13A	10248405	NELAP	LA
5856 - Coronene	EPA TO-13A	10248405	NELAP	LA
5895 - Dibenz(a,h)anthracene	EPA TO-13A	10248405	NELAP	LA
6265 - Fluoranthene	EPA TO-13A	10248405	NELAP	LA
6270 - Fluorene	EPA TO-13A	10248405	NELAP	LA
6315 - Indeno(1,2,3-cd)pyrene	EPA TO-13A	10248405	NELAP	LA
5005 - Naphthalene	EPA TO-13A	10248405	NELAP	LA
6608 - Perylene	EPA TO-13A	10248405	NELAP	LA
6615 - Phenanthrene	EPA TO-13A	10248405	NELAP	LA
6665 - Pyrene	EPA TO-13A	10248405	NELAP	LA

Non Potable Water

Analyte	Method Name	Method Code	Type	AB
NONE	NONE	NONE	NONE	NONE

Solid Chemical Materials

Analyte	Method Name	Method Code	Type	AB
NONE	NONE	NONE	NONE	NONE

Biological Tissue

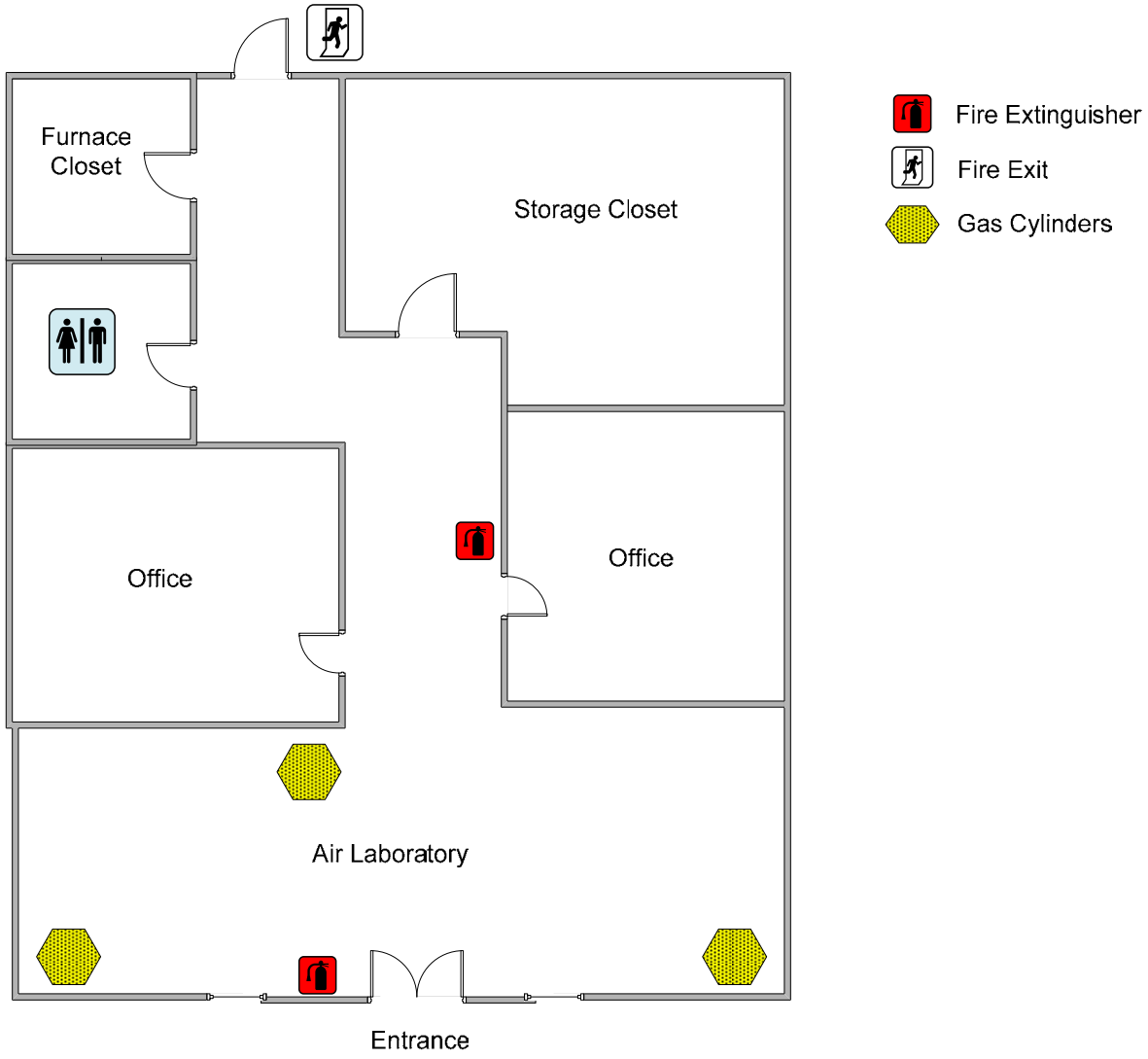
Analyte	Method Name	Method Code	Type	AB
NONE	NONE	NONE	NONE	NONE

Clients and Customers are urged to verify the laboratory's current certification status with the Louisiana Environmental Laboratory Accreditation Program.

Appendix C - Laboratory Floor Plans

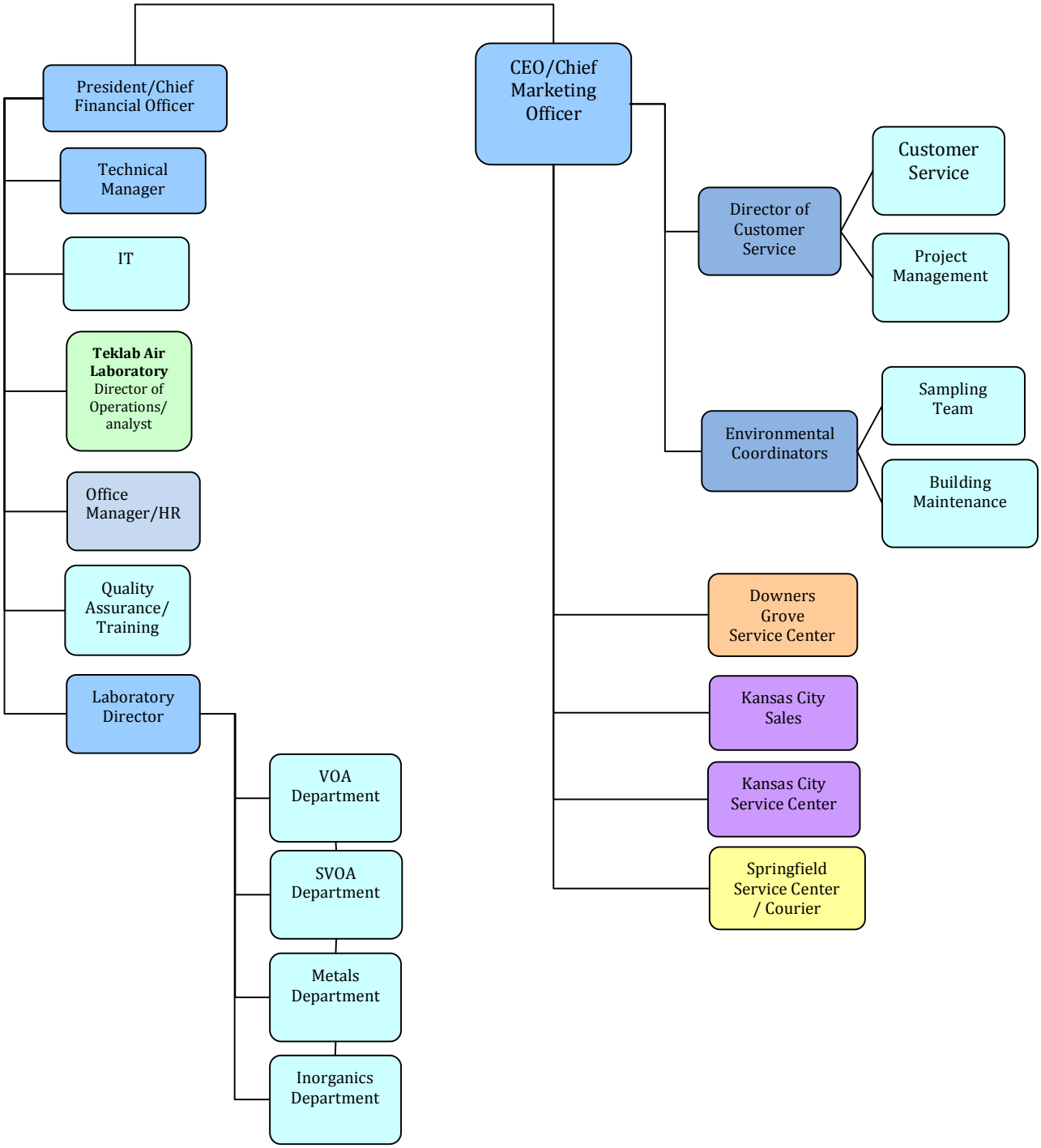
C.1 Collinsville (Corporate)

C.2 Collinsville Air Laboratory

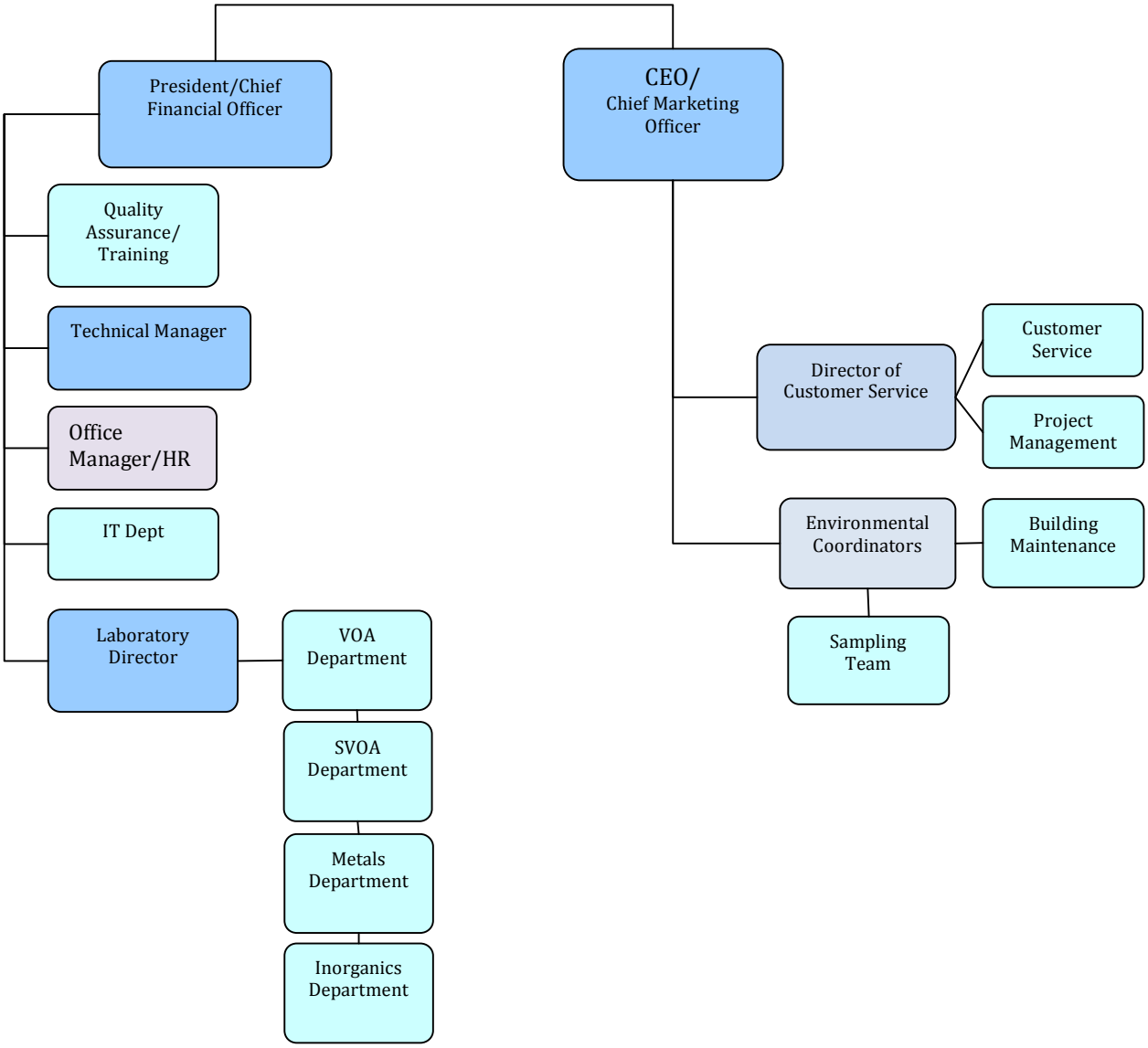


Appendix B
Laboratory Organization Charts

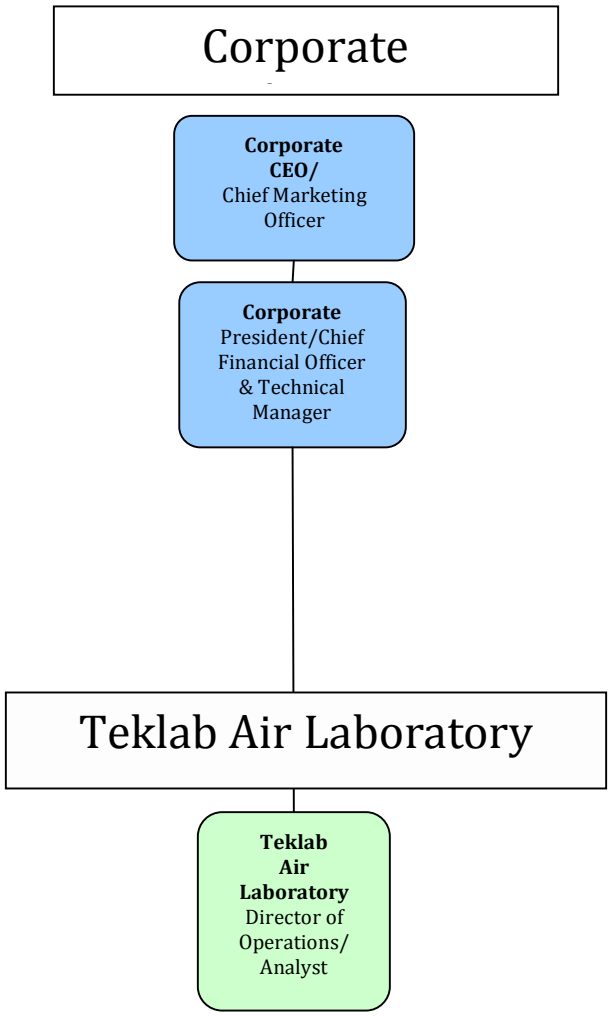
B.1 Teklab Inc



B.2 Teklab Inc – Collinsville (Corporate)



B.3 Teklab Inc – Teklab Air Laboratory



Appendix A

Ethics and Data Integrity Policy

Ethics, Legal Responsibility, & Conflict of Interest (Rev. B)

Effective Date: 11/14/05
Reference: TNI Standard – Quality Systems

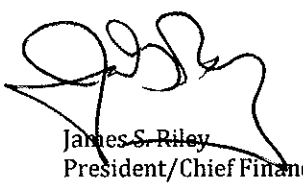
To all Teklab, Inc. Employees, Customers and Vendors,

Teklab, Inc. will not tolerate any improper, unethical or illegal actions by its employees, customers or vendors. No customer, employee or vendor shall enter into any agreement (written or implied) and shall not engage in activities which would put any commercial, financial or other pressure on an employee of Teklab, Inc. which might adversely affect the quality of that employees work. Any employee determined to be involved in such behavior will be disciplined, up to and including termination of employment at Teklab, Inc. Any customer or vendor determined to be involved in such behavior will be sanctioned, up to and including termination of any future business with Teklab, Inc.

Teklab, Inc. will use the following procedures to proactively detect any improper, unethical or illegal actions:
1.) Internal data reviews and audits
2.) Daily interactions of the management staff with employees
3.) Daily interactions with customers and vendors
4.) Confidentiality for individuals reporting potential problems (unless the problem develops to the point where Teklab, Inc. no longer has control (i.e. court orders, etc.))
5.) Internal investigations when employees identify potential problems
6.) External investigations by the appropriate authorities, when necessary
7.) Prosecution when appropriate

All Teklab, Inc. personnel must be free from any commercial, financial and any other pressures that might adversely affect the quality of their work. Teklab, Inc. shall use the following procedures to proactively detect any of those pressures:
1) Daily interactions of the management staff with employees
2) Daily interactions with customers and vendors
3) Confidentiality for individuals reporting potential problems (unless the problem develops to the point where Teklab, Inc. no longer has control (i.e. court orders, etc.))
4) Internal investigations when employees identify potential problems
5) External investigations by the appropriate authorities, when necessary
6) Prosecution when appropriate

We at Teklab, Inc. take our reputation and the law seriously. We will not tolerate any improper, unethical or illegal actions. We will turn people in to the proper authorities and/or press charges, when appropriate.



James S. Riley
President/Chief Financial Officer